84-130 (1)

No. 84-

Office-Supreme Court, U.S.
FILED
JUL 17 1984
ALEXANDER L. STEVAS,
CLERK

IN THE

Supreme Court of the United States

October Term, 1984

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

v.

ROCHE PRODUCTS, INC.,

Respondent.

On Writ of Certiorari to the United States
Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Robert V. Marrow
Salon, Marrow, Dyckman & Trager
Attorneys for Petitioner
Bolar Pharmaceutical Co., Inc.
41 East 42nd Street
New York, New York 10017
(212) 661-7100

78 pp

Questions Presented

1. Is experimental use of a patented invention, which does not affect the patent holders' exclusive exploitation of the invention during the patent term, prohibited by the patent law because the experimentor intends to use the results of the experiment for a business purpose after patent expiration?

2. Can a patent holder extend its monopoly over a prescription drug for two years or more after the patent expires by prohibiting others from using the drug in experiments conducted to satisfy Food and Drug Administration pre-marketing requirements?

Parties to the Proceeding Below

The parties named in the caption are the only parties to this action.

Pursuant to Supreme Court Rule 28.1, petitioner Bolar Pharmaceutical Co., Inc. identifies its parent companies, subsidiaries and affiliates as follows:

Bolar, Inc.
Superior Label Corp.

TABLE OF CONTENTS

PAGE

Questions Presented I

Parties to the Proceeding Below II

Table of Authorities VI

Opinions Below 1

Jurisdiction 2

Constitutional Provisions and Statutes Cited 2

Statement of the Case 2

Reasons for Granting the Writ 7

I—The Decision Below Extends Drug Patent Monopolies for Indefinite Periods Beyond Patent Expiration, and Conflicts With the Constitution, the Patent Law and Decisions of This Court 7

II—The Court of Appeals Failed to Recognize That the Patent Law Does Not Prohibit Unlicensed Uses Which Do Not Affect the Patent Holder's Rights 11

III—FDA Related Experiments Do Not Interfere With Roche's Rights 13

PAGE

IV—The Experimental Use Doctrine Should Be Defined by This Court to Permit Scientific Experimentation Which Does Not Interfere With the Patent Grant Although the Ultimate Motive of the Experimentor Is to Use the Results of His Experiments for Business Purposes After Patent Expiration 16

Conclusion 20

Appendices:

A—Opinion of the United States Court of Appeals for the Federal Circuit, *Roche Products, Inc.* v. *Bolar Pharmaieutical Co., Inc.*, 733 F.2d 858 (1984) 1a

—Order of the United States Court of Appeals for the Federal Circuit, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.*, App. No. 84-560 (Nov. 4, 1983) 19a

—Order of the United States Court of Appeals for the Federal Circuit, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.*, App. No. 84-560 (Oct. 24, 1983) 20a

B—Opinion of the United States District Court for the District of New Jersey, *Roche Products, Inc.* v. *SST. Corp., Bolar Pharmaceutical Co. and Robert Shulman* (sic), Civ. No. 83-2809 (Sarokin, J.) (Sept. 2, 1983) 21a

—Memorandum and Order of the United States District Court for the Eastern District of New York, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.*, 472 F. Supp. 255 (1983) 31a

PAGE

C—Judgment of the United States District Court for the Eastern District of New York, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.*, CV 83-4312 (Wexler, J.) 38a

—Judgment of the United States Court of Appeals for the Federal Circuit, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.* (April 23, 1984) 39a

D—U.S. Const. Art. I, Sec. 8, Cl. 8 .... 40a

—21 U.S.C. 355(a)(b) 40a

—35 U.S.C. 154 .... 41a

—35 U.S.C. 271 .... 41a

—35 U.S.C. 283 .... 41a

E—224 Science 1080—(06/08/84) (American Association of the Advancement of Science) 42a

TABLE OF AUTHORITIES

PAGE

Cases:

Arko Argate Company v. Master Marble Company, 18 F.Supp. 305 (N.D.W.Va. 1937) ... 12

Brulotte v. Thys Co., 379 U.S. 29 (1964) ... 9, 15

Cabell v. Markam, 148 F.2d 737 (2d Cir.), *aff'd,* 326 U.S. 464 (1945) ... 11
Celotex Corporation v. V.E. Power Door Corp., 204 U.S.P.Q. 636 (E.D.N.Y. 1979) ... 12

Kaz Manufacturing Co., Inc. v. Chesebrough-Pond's, Inc., 211 F.Supp. 815 (S.D.N.Y. 1962), *aff'd,* 317 F.2d 679 (2d Cir. 1963) ... 12, 13
Kellogg Co. v. National Biscuit Co., 305 U.S. 111 (1938) ... 8

Levin v. Ripple Twist Mills, 416 F.Supp. 876 (E.D.Pa. 1976), *appeal dismissed,* 549 F.2d 795 (3d Cir. 1977) ... 12

Maxon Premix Burner Company, Inc. v. Eclipse Fuel Engineering Co., 471 F.2d 308 (7th Cir. 1972) ... 12
Mercoid Corporation v. Mid-Continent Investment Co., 320 U.S. 661 (1944) ... 12, 14

Pfizer, Inc. v. International Rectifier Corp., 217 U.S. P.Q. 157 (C.D. Cal. 1982) ... 18

Scott Paper Co. v. Marcalus Mfg. Co., 326 U.S. 249 (1945) ... 8, 12, 15
Seymour v. Osborne, 78 U.S. 516 (1870) ... 7
Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169 (1895) 8

PAGE

Upjohn Mfg. Co. v. Schweiker, 681 F.2d 480 (6th Cir. 1982) 9, 16
U.S. v. Generix, —— U.S. ——, 103 S.Ct. 1610, 75 L.Ed.2d 198 (1983) 3

Virginia State Board of Pharmacy v. Virginia Citizens' Consumer Counsel, 425 U.S. 748 (1976) 9

Walker Process Equipment Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965) 7

No. 84-

IN THE

Supreme Court of the United States

October Term, 1984

Bolar Pharmaceutical Co., Inc.,
Petitioner,
v.
Roche Products, Inc.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioner hereby requests that this Court issue a writ of certiorari to review a judgment of the United States Court of Appeals for the Federal Circuit entered April 23, 1984.

Opinions Below

The opinion of the United States Court of Appeals for the Federal Circuit, which is reported at 733 F.2d 858 (Fed. Cir. 1984), is reprinted as Appendix A, *infra* pp. 1a-

18a of this petition. The opinion of the District Court, reported at 472 F.Supp. 255 (E.D.N.Y. 1983), is reprinted as Appendix B, *infra* pp. 31a-37a.*

Jurisdiction

Review of the Court of Appeals judgment reversing the district court and remanding this case to that court is within this Court's jurisdiction under 28 U.S.C. Section 1254(1). The Court below had jurisdiction premised on 28 U.S.C. Section 1338(a).

Constitutional Provisions and Statutes Cited

United States Constitution Article I, Section 8, Clause 8

Title 21 United States Code Section 355(a)(b)

Title 35 United States Code Section 154

Title 35 United States Code Section 271(a)

Title 35 United States Code Section 283

The pertinent text of these provisions is set forth in Appendix D, *infra* at pp. 40a, 41a.

Statement of the Case

Flurazepam hydrochloride (flurazepam hcl) is the active chemical ingredient in a successful sleeping pill, prescribed for insomnia and sold in the United States exclusively by Roche Products, Inc. (Roche) under the trade name Dalmane. Roche patented flurazepam hcl on January 15, 1967, and, therefore, its patent expired after seventeen years, on January 15, 1984. 35 U.S.C. 154.

---

* Pages in the Appendix will be referred to by the page number followed by the letter "a".

Bolar Pharmaceutical Co., Inc. (Bolar), a generic drug manufacturer, wanted to begin making and selling generic flurazepam hcl tablets in competition with Roche, as soon as possible after Roche's patent expired.

The development of a generic equivalent to a brand name drug product requires a substantial amount of research and development, testing and experimentation by the generic manufacturer. A generic drug is not simply a copy of the originator. This Court has recently held that a generic drug is a "new drug" and that the Food and Drug Administration (FDA) must approve a New Drug Application (NDA) before a generic drug can be sold, despite the fact that its active ingredients are identical to the originator's. *U.S.* v. *Generix*, —— U.S. ——, 103 S.Ct. 1610, 75 L.Ed.2d 198 (1983). The FDA must be satisfied that the new generic drug is safe and effective (21 U.S.C. 355), i.e., that it delivers the active ingredient to the site of drug action in proper potency and at the proper time. (34a)

A generic drug is a "new drug" despite the fact that its active ingredient is identical to the brand name drug because the inactive ingredients are almost always different. Inactive ingredients, such as fillers, lubricants, binders, releasing agents and sustained release agents, can affect the way that the active ingredient works in the body. Inactive ingredients are trade secrets—Bolar does not know what inactive ingredients are in Roche's Dalmane. The task of Bolar's research and development is to discover a combination of inactive ingredients that, when mixed with the active ingredient, will meet all the FDA's requirements of safety and effectiveness and will work in the body in the same way as Roche's product.

The process of developing a generic product and obtaining FDA approval takes about two years. Bolar must perform dissolution studies, stability studies, bioavailability and bioequivalency studies, and must develop methods to establish that the data produced by these studies accurately support the conclusion that its flurazepam hcl is safe and effective, and will work in the human body much the same as Dalmane.

Because this process of developing and testing generic products in order to obtain FDA approval takes approximately two years, it has been the practice and custom in the pharmaceutical industry for generic companies to begin testing their products and applying for FDA approval well in advance of patent expiration, so that they can have the approval and be ready to enter the market and compete with the brand name product as soon as possible after the patent on the brand name product expires.

In early 1983, following this custom and practice, Bolar purchased five (5) kilograms of flurazepam hcl from a source other than Roche and began testing the product. To the surprise of Bolar and the rest of the generic drug industry, Roche sued Bolar to prohibit Bolar's use of the product in tests and experiments conducted solely for FDA approval.* Five (5) kilograms is not a commercially viable quantity to manufacture a product for sale. Roche knew that Bolar's use of the product was intended only to permit

---

* Roche brought the action in the U.S. District Court, District of New Jersey. There Judge Sarokin granted a temporary restraining order on the same day Roche moved for that relief, noting that his order did not preclude a different decision by the judge assigned to the case after full consideration. (21a) The case was transferred to the Eastern District of New York on Bolar's motion for a change of venue (28a), and assigned to Judge Wexler.

Bolar to enter the market after patent expiration, and that the effect of Roche's suit, if successful, would be to delay the start of experimentation for FDA approval until after patent expiration, thereby giving Roche and other research oriented pharmaceutical companies an additional period of indefinite duration after patent expiration during which Roche and others like it would have exclusive access to the American market for their drugs. (34a)

Bolar defended the action on the grounds that the Constitution (art. I, section 8, cl. 8) and the Patent Statute (35 U.S.C. 154) state that patent protection can be granted only for "limited times", specifically seventeen years, and that Roche was seeking *de facto* extension of its patent monopoly for an indefinite period in excess of seventeen years, possibly nineteen years or more. Furthermore, Roche's attempt to extend its monopoly into the post-expiration period was based upon requirements imposed on Bolar by the Food, Drug & Cosmetic Act, which is designed to insure safe and effective pharmaceutical products, and not to give a developer of a pioneer product a monopoly of indefinite duration.

Roche claimed Bolar's use of the product was prohibited by the section of the patent law which gives the patent holder the right to exclude others from "making, *using* or selling" the patented invention for the life of the patent. 35 U.S.C. 154 (emphasis added). Bolar countered that the use prohibited by the patent law did not extend to the kind of experimentation engaged in by Bolar, which had no effect on the legitimate rights of the patent holder during the seventeen year life of the patent.

The District Court dismissed Roche's complaint, finding that Bolar's experiments would not be a prohibited use of Roche's patented product, and that their effect on Roche's patent rights were *de minimis.* (36a)

The Court of Appeals for the Federal Circuit rejected Bolar's contentions and reversed the District Court, using language that prohibits not only Bolar's experimental use of flurazepam hcl, but also endangers scientific experimentation with any patented product if the ultimate purpose of the experiments is business related:

> "Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the '053 patent. Bolar may intend to perform 'experiments,' but unlicensed experiments conducted with a view to the adaption of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention." (9a)

The Court of Appeals remanded the case to the District Court solely for the imposition of a remedy.

The Court of Appeals decision extends for years after patent expiration the monopolies of patent holders in the pharmaceutical industry by misinterpreting the section of the patent law which prohibits unlicensed use of a patented product. That prohibition has traditionally been applied to uses which interfere with the interest of the patent holder in exploiting his invention, and not to innocuous uses, such as experimental use, which do not affect the right of the patent holder to exploit his invention. For decades such experimental use has gone unchallenged by Roche and all other large pharmaceutical companies, despite their knowledge of its existence based on hundred of FDA approvals issued before, or just after patent expiration.

What follows is an analysis of the errors made by the Court of Appeals in finding Bolar's use to be patent infringement, and a discussion of the compelling reasons to review the Court of Appeals decision based on its effect on the pharmaceutical industry, scientific research, government purchases of drug products and the cost of medicine to that segment of the public least able to afford an extension of drug monopolies, the ill and the elderly.

Reasons for Granting the Writ

I

The Decision Below Extends Drug Patent Monopolies for Indefinite Periods Beyond Patent Expiration, and Conflicts With the Constitution, the Patent Law and Decisions of This Court.

The Constitution authorizes Congress to secure "for limited times" to inventors "the exclusive right" to their inventions and discoveries. U.S. Const., art. I, sec. 8, cl. 8.

Because a patent is an exception to both the general prohibition against monopolies and the valued right of access to a free and open market, *Walker Process Equipment Inc.* v. *Food Machinery & Chemical Corp.,* 382 U.S. 172 (1965), it is by its very nature affected with a public interest. *Seymour* v. *Osborne,* 78 U.S. 516, 533 (1870). The law is carefully designed to accommodate the tension between two conflicting public policies—one to encourage invention and the other to foster competition by making the invention available to the public. Invention is encouraged by granting a patent monopoly, competition is fostered by requiring disclosure of the patented invention and limiting the patent monopoly. The Congress has determined seventeen years to be the appropriate monopoly period to encourage invention. 35 U.S.C. 154.

By interpreting the patent statute to prohibit experimental use of patented chemical entities by drug companies which must have FDA approval to sell their competing products, the decision of the court below adds an indefinite period to the 17 year patent grant.

This decision conflicts with the Constitution because it gives the patentee a monopoly of indefinite duration where the Constitution mandated that the exclusive rights granted by the patent be "for limited times." It also conflicts with the statute itself, which limits patent duration to 17 years.

Furthermore, the decision conflicts with this Court's consistent view that:

> ". . . any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws."
>
> *Scott Paper Co.* v. *Marcalus Co.,* 326 U.S. 249, 256, 90 L.Ed. 47, 51, 66 S.Ct. 101

See also Singer Mfg. Co. v. *June Mfg. Co.,* 163 U.S. 169, 185, 41 L.Ed. 118, 124, 16 S.Ct. 1002 (1895); *Kellogg Co.* v.

National Biscuit Co., 305 U.S. 111, 118, 83 L.Ed. 73, 78, 59 S.Ct. 109 (1938); *Brulotte* v. *Thys Co.,* 379 U.S. 29, 31, 13 L.Ed.2d 99, 101, 85 S.Ct. 176.

In the case at bar, the public interest in a free and open market after patent expiration is particularly acute because of the nature of the product involved, a prescription drug. Competition between generic drug manufacturers and name-brand drug companies significantly reduces the cost of medication for those most in need, usually the sick and the elderly. *Virginia State Board of Pharmacy* v. *Virginia Citizens' Consumer Counsel,* 425 U.S. 748, 763 (1976).

It is not the purpose of the Food, Drug & Cosmetic Act, or the FDA regulations promulgated thereunder, to extend pioneer drug manufacturers' exclusive dominion over the American market.

> "The Federal Food, Drug and Cosmetic Act and the underlying regulations governing the approval for the marketing of new drugs were not intended to provide patent-like protection for a seller who has gained approval of a pioneer drug application."
>
> *Upjohn Mfg. Co.* v. *Schweiker,* 681 F.2d 480 (6th Cir. 1982)

The Court of Appeals noted the enormous importance of the issue presented:

> "At stake in this case is the length of time a pharmaceutical company which has a patent on the active ingredient in a drug can have exclusive access to the American market for that drug." (1a, 2a).

In effect, the Court of Appeals has extended Roche's "exclusive access to the American market" for an indefinite period *after* patent expiration. The legitimate competition, envisaged by the framers of the Constitution, who required that patents be of *limited* duration (U.S. Const., art. I, sec. 8, cl. 8), and by the legislature, which fixed 17 years as the appropriate length of a patent monopoly (35 U.S.C. 154), will be indefinitely delayed for substantial periods of time if experimenation with drug products requiring FDA pre-market approval is prohibited until patent expiration.* A holding that Bolar's FDA related experimentation with flurazepam hcl would be patent infringement extends Roche's monopoly and therefore frustrates an essential purpose of the patent laws, to make inventions available to the public when patents expire.

The decision below conflicts with applicable provisions of the Constitution, the patent statute and with every applicable decision of this Court. It should be reviewed.

---

* It is also significant that the Court of Appeals decision and the American patent laws do not apply to Canadian and other foreign manufacturers of generic drugs. These generic firms will be able to do the necessary experimentation and submit applications for pre-marketing approval to the FDA during the patent term, while American generic drug companies must wait until after patent expiration to begin experimentation. This obviously gives foreign generic drug companies a tremendous advantage over domestic companies (an entry into the United States market approximately two years prior to American companies), a result which could not have been intended by the framers of the Constitution or the patent statute. Another unintended consequence of the Court of Appeals decision will be the shifting of research and development of American generic drug manufacturers from their own laboratories to foreign research facilities.

II

The Court of Appeals Failed to Recognize That the Patent Law Does Not Prohibit Unlicensed Uses Which Do Not Affect the Patent Holder's Rights.

The patent law states that a patent holder can, "exclude others from making, using or selling the invention . . ." 35 U.S.C. 154. Although this broad prohibition literally applies to all making, using or selling of the patented invention, Judge Learned Hand's observation on statutory construction (noted in the opinion below) is particularly applicable here:

> "[I]t is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing: be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning."
>
> *Cabell* v. *Markam*, 148 F.2d 737, 739 (2d Cir.), *aff'd*, 326 U.S. 464 (1945)

The "surest guide" to the meaning of the use prohibition is the purpose and object of the patent law.

For more than a century courts have considered the underlying purpose and object of patent grants in determining which uses interfere with that purpose and are therefore infringements, as well as which uses do not disturb the interests of the patentee, and therefore are non-infringing.

The patent law has a dual purpose, to encourage invention and to provide public disclosure of inventions. *Mercoid Corporation* v. *Mid-Continent Investment Co.*, 320 U.S. 661, 665, 64 S.Ct. 268 at 271, 88 L.Ed. 376 (1943); *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249, 255, 90 L.Ed. 47, 51 (1945). The means employed to accomplish this purpose is the grant of, "a right to be free from competition in the practice of the invention," for a limited time. *Mercoid, supra*, 320 U.S. at 665.

It has long been recognized that it is not necessary or desirable to prohibit all uses of a patented invention in order to secure to the patent holder the exclusive right to exploit his creation. A use which does not disturb the patentee's rights to be free from competition in the practice of his invention does not infringe the patent. Permitted uses of the patented invention have been characterized as experimental, *de minimis*, non-infringing, outside the scope of the patent or in the public interest. *Kaz Manufacturing Co., Inc.* v. *Chesebrough-Pond's, Inc.*, 211 F.Supp. 815 (S.D. N.Y. 1962), *aff'd*, 317 F.2d 679 (2d Cir. 1963); *Celotex Corporation* v. *V.E. Power Door Corp.*, 204 U.S.P.Q. 636 (E.D.N.Y. 1979); *Levin* v. *Ripple Twist Mills*, 416 F.Supp. 876, 881 n. 9 (E.D.Pa. 1976), *appeal dismissed without opinion*, 549 F.2d 795 (3d Cir. 1977); *Arko Argate Company* v. *Master Marble Company*, 18 F.Supp. 305 (N.D.W.Va. 1937); *Maxon Premix Burner Company, Inc.* v. *Eclipse Fuel Engineering Co.*, 471 F.2d 308 (7th Cir. 1972).

Clearly the patent law does not prohibit all unlicensed uses of an invention, and the basis for permitting a particular unlicensed use is that such use does not interfere with or disturb the legitimate right of the patentee to be free from competition in practicing his invention during the patent term. Bolar's use of flurazepam hcl is in this category. (See Point III)

III

FDA Related Experiments Do Not Interfere With Roche's Rights.

Bolar's use of flurazepam hcl does not threaten or disturb Roche's exclusive right to practice its invention, i.e., to make, use and sell the drug for therapeutic purposes during the life of the patent. Every tablet which was made, used or sold as a sleeping pill in the United States during the life of the patent was Roche's. FDA related experimentation does not disturb in the slightest Roche's exclusive access to the American market, which provides the incentive to invent at the heart of the patent law.

Roche's patent, "insures against another doing substantially the same thing in substantially the same way as the patentee." 69 C.J.S. Patents, p. 72, quoted in *Kaz Manufacturing Co.* v. *Chesebrough-Pond's, Inc., supra.* FDA related experiments do not infringe the patent because they do not use the patented drug in the same way as the patentee uses the drug.

Professor Robinson defines the interest of the patentee as follows: "The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others." (W. Robinson, *The Law of Patents for Useful Inventions,* Section 898 (1890)). This Court has defined the patentee's interest as, "a right to be free from competition in the practice of the invention." *Mercoid Corp.* v. *Mid-Continent Investment Co., supra,* 320 U.S. at 665. Inherent in the very term "practice the invention" (a term of art frequently used by courts, attorneys and scholars in connection with patents) is a type of use which exploits the invention. Experimenting with the product is not "practicing the invention". Roche made, used and sold the drug for therapeutic purposes, Bolar did not. Bolar did not practice the invention; rather it wanted to use the product in experiments to develop data for its FDA application, a use that has no effect on Roche during the life of the patent. Whether characterized as experimental, *de minimis,* or otherwise, Bolar's experiments were non-infringing use.

The Court of Appeals found FDA related experiments infringing because they are conducted, "for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." (9a) Clearly, the court below focused on Bolar's motives instead of the effect on Roche's patent rights. This emphasis on the motive of the accused infringer leads to error because the objectives of the patent law are directed to encouraging innovation by benefiting the patentee. Focusing on the motive of the alleged infringer, the court misses the salient point; Bolar's experimental use does not disturb the benefits granted to Roche during the patent term, and therefore Bolar's use does not diminish the incentive to invent.

By performing experiments for its FDA application before Roche's patent expired, Bolar may gain the advantage of entering the market earlier after patent expiration than it otherwise would if it had to wait for patent expiration to begin its experiments. Roche points to this advantage sought by Bolar, which can be substantial, and argues that the use, and Roche's injury, are not *de minimis.* In making this argument, Roche fails to recognize an essential distinction between the period before patent expiration and the period after its patent expires. Roche's only injury occurs as the result of competition after the patent expires, and Roche has no right to be free from competition in that period. As the Supreme Court stated in *Scott Paper Co.* v. *Marcalus Co.,* 326 U.S. 249, 256 (1965):

> ". . . any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws."

See also Brulotte v. *Thys Co.,* 379 U.S. 29 (1964).

FDA related experiments, which take place during the patent period, are non-infringing because they do not disturb Roche's right to fully exploit the invention. The fact that those pre-patent expiration experiments permit Bolar to enter the marketplace and compete with Roche at an earlier date cannot form the basis of any claim of patent infringement because competition takes place exclusively after the patent expires.

Roche also argued below that Bolar's FDA related use would infringe Roche's right to license that use, and was therefore commercially detrimental to Roche's patent rights. This contention ignores the reality that Roche never has and never would license such use. Moreover, it is repugnant to the very purposes of the FDA premarketing regulations to permit Roche to profit from FDA regulations which were intended only to assure safe and effective drugs for the public, rather than to swell brand name drug companies' profits. *See Upjohn Mfg. Co. v. Schweiker*, 681 F.2d 480 (6th Cir. 1982).

As Judge Wexler found after trial, FDA related experiments before patent expiration are non-infringing because they do not disturb or impinge upon Roche's rights to be free of competition in the practice of its invention during the 17 years covered by the patent grant. (37a)

IV

The Experimental Use Doctrine Should Be Defined by This Court to Permit Scientific Experimentation Which Does Not Interfere With the Patent Grant Although the Ultimate Motive of the Experimentor Is to Use the Results of His Experiments for Business Purposes After Patent Expiration.

It is essential that the "experimental use" doctrine be reviewed by this Court. Experimental use as defined by the Court of Appeals (i.e., experimentation solely for amusement, to satisfy idle curiosity or for strictly philosophical purposes [9a]) is meaningless, because virtually all serious research and experimentation has some ultimate business purpose. The very purpose of the patent law, to encourage research, experimentation and invention, is turned on its head by this decision which can effectively curtail much useful scientific creativity.

In the pharmaceutical industry the Court of Appeals decision delays for years research and development to create "new drugs"—generic equivalents of expensive brand name products—despite the fact that such research and development has no effect on the patent holder's exclusive right to practice his invention and profit from that practice during the patent term.

Prior to this decision, experimental projects by generic drug companies to develop inexpensive equivalents to brand name drug products were accepted by the pharmaceutical community as a lawful and permissible use of patented products. The FDA has approved pre-marketing applications for generic companies on numerous drug products *prior to patent expiration.* Those applications obviously were based on data obtained from experimental use of the patented products prior to patent expiration. At this very moment most, if not all, generic drug manufacturers have pending with the FDA pre-marketing applications for patented drugs based on data obtained from experiments using the patented product. The decision can create chaos in the generic drug industry if the experimentation upon which hundreds of FDA approvals have previously been granted suddenly becomes illegal.

The magnitude of this problem is immense because the Court of Appeals decision requires federal courts to grant substantial damages or injunctions in all cases where experimentation has produced data now contained in pending FDA applications. For example, Roche has already commenced demanding from all generic companies that have experimented with diazepam hcl (the active ingredient in Valium, the patent for which expires in 1985) information concerning their FDA related use of that drug ingredient. The Court of Appeals decision creates chaos where there had previously been a common understanding in the industry that experimentation with such drugs was a protected use leading to competition after patent expiration. The enormity of the chaos is truly staggering when the flurazepam hcl and diazepam hcl situations are multiplied by the number of drugs in which generic companies correctly assumed their experimentation was lawful.

It never even occurred to patent holders to question the right of generic companies to use patented products in FDA mandated experiments, until the aberrant case of *Pfizer, Inc.* v. *International Rectifier Corp.*, 217 U.S.P.Q. 157 (C.D. Cal. 1982) was reported. That case was based upon an unusual "defiance of court decrees" (15a) by the defendant, and arose in a context far different from that in the case at bar or the common situation where generic companies have experimented with patented products as part of the ordinary course of business accepted as proper for decades by all segments of the pharmaceutical industry. The Court of Appeals decision has taken the limitation on experimental use imposed upon a defiant infringer in *Pfizer,* and imposed it upon the entire generic drug industry.

Moreover, the broad language adopted by the Court of Appeals extends the limitation on the experimental use doctrine to the scientific community in general, where research using patented products has always been accepted as lawful. That belief is suddenly brought into question by the Court of Appeals decision. (*See Science* Vol. 224, 8 June 1984, p. 1080, published by the American Association of the Advancement of Science, Appendix E.)

These limitations on experimental use of patented products are based solely on the acknowledged fact that the results of the experiments will have a business related use after patent expiration. (9a) However, it is not the intent of the experimentor, be he dilettante or businessman, that he should control the application of the experimental use doctrine; rather, the effect of the experiments on the patent holder should be the criterion. Even Professor Robinson, whose language the Court of Appeals adopts to define the experimental use doctrine, recognized that there is, "No Act of Infringement Unless it Affects the Pecuniary Interests of the Owner of the Patented Invention."

> "[T]he interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others."
>
> (W. Robinson, *The Law of Patents and Useful Inventions,* Section 998 (1890), quoted by the C.A.F.C. at 7a)

Only by judging experimental use by that standard (i.e., does it diminish the emoluments which the patentee does or might receive?), and not by the intent of the experimentor, can a court determine whether the act of the experimentor diminishes the patent grant by interfering with or disturbing the commercial monopoly which provides the incentive to invent at the core of the patent law.

It has traditionally been for the courts, not the legislature, to define experimental use. It is disingenuous for the Court of Appeals to say that the patent statute is clear on its face, and it is up to the Congress, not the courts, to analyze the experimental use doctrine as it applies to this case. If that were true, there would be no experimental use doctrine and any use would be actionable, regardless of the experimentor's intent or the *de minimis* effect on the patent grant.

Unless reversed, this decision will inhibit the advancement of scientific knowledge and the development of useful drugs and inventions which the patent law was intended to foster and encourage.

Conclusion

This case does not involve technical questions of patent validity as to which the court might defer to the scientific expertise of the members of the C.A.F.C. Rather, general questions of policy and jurisprudence are presented by this case.

A federal court of appeals has decided an important question of federal law which has not been, but should be settled by this Court. The decision below conflicts with applicable decisions of this Court by extending Roche's patent monopoly for an indefinite period beyond the patent term.

It is respectfully requested that a Writ of Certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit.

Respectfully submitted,

ROBERT V. MARROW
SALON, MARROW, DYCKMAN & TRAGER
Attorneys for Petitioner
Bolar Pharmaceutical Co., Inc.

APPENDICES

APPENDIX A

Decision of United States Court of Appeals for the Federal Circuit

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Appeal No. 84-560

ROCHE PRODUCTS, INC.,
Appellant,
v.
BOLAR PHARMACEUTICAL CO., INC.,
Appellee.

DECIDED: April 23, 1984

Before MARKEY, *Chief Judge,* NICHOLS, *Senior Circuit Judge,* and KASHIWA, *Circuit Judge.*

NICHOLS, *Senior Circuit Judge.*

This is an appeal from a judgment entered on October 14, 1983, in which the United States District Court for the Eastern District of New York held United States Patent No. 3,299,053 not infringed and denied relief. We *reverse* and *remand.*

I

At stake in this case is the length of time a pharmaceutical company which has a patent on the active ingredient in a drug can have exclusive access to the American market for that drug. Plaintiff-appellant Roche Products, Inc. (Roche), a large research-oriented pharmaceutical company, wanted the United States district court to enjoin Bolar Pharmaceutical Co., Inc. (Bolar), a manufacturer of generic drugs, from taking, during the life of a patent, the statutory and regulatory steps necessary to market, after the patent expired, a drug equivalent to a patented brand name drug. Roche argued that the *use* of a patented drug for federally mandated premarketing tests is a *use* in violation of the patent laws.

Roche was the assignee of the rights in U.S. Patent No. 3,299,053 (the '053 patent), which expired on January 17, 1984. The '053 patent, which issued on January 17, 1967, is entitled "Novel 1 and/or 4-substituted alkyl 5-aromatic-3H-1,4-benzodiazepines and benzodiazepine-2-ones." One of the chemical compounds claimed in the '053 patent is flurazepam hydrochloride (flurazepam hcl), the active ingredient in Roche's successful brand name prescription sleeping pill "Dalmane."

In early 1983, Bolar became interested in marketing, after the '053 patent expired, a generic drug equivalent to Dalmane. Because a generic drug's commercial success is related to how quickly it is brought on the market after a patent expires, and because approval for an equivalent of an established drug can take more than 2 years, Bolar, not waiting for the '053 patent to expire, immediately began its effort to obtain federal approval to market its generic version of Dalmane. In mid-1983, Bolar obtained from a foreign manufacturer 5 kilograms of flurazepam hcl to form into "dosage form capsules, to obtain stability data, dissolution rates, bioequivalency studies, and blood serum studies" necessary for a New Drug Application to the United States Food and Drug Administration (FDA).

On July 28, 1983, Roche filed a complaint in the United States District Court for the District of New Jersey against three parties: Bolar, Bolar's principal officer, and the importer of the infringing flurazepam hcl. Only Bolar remains a party defendant. Roche sought to enjoin Bolar from using flurazepam hcl for any purpose whatsoever during the life of the '053 patent. When Bolar stated during discovery, on August 30, 1983, that it intended immediately to begin testing its generic drug for FDA approval, Roche moved for and was granted a Temporary Restraining Order, on September 2, 1983.

On September 26, 1983, Bolar was granted a change of venue and the case was transferred to the United States District Court for the Eastern District of New York. That court consolidated Roche's motion for a preliminary injunction with the trial on the merits pursuant to Fed. R. Civ. P. 65(a)(2) (both parties had stipulated to all the pertinent facts so no testimony was necessary) and on October 11, 1983, issued a Memorandum and Order denying Roche's application for a permanent injunction. The court held that Bolar's use of the patented compound for federally mandated testing was not infringement of the patent in suit because Bolar's use was *de minimis* and experimental. The court entered judgment for Bolar on October 14, 1983, and Roche filed its notice of appeal that same day.

II

The district court correctly recognized that the issue in this case is narrow: does the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable? The district court held that it does not. This was an error of law.

III

A

When Congress enacted the current revision of the Patent Laws of the United States, the Patent Act of 1952, ch. 950, 66 Stat. 792 (codified at 35 U.S.C.), a statutory definition of patent infringement existed for the first time since section 5 of the Patent Act of 1793 was repealed in 1836. Title 35 U.S.C. § 271(a) incorporates the disjunctive language of the statutory patent grant which gives a patentee the "right to exclude others from making, using, or selling" a patented invention, 35 U.S.C. § 154. Congress states in section 271(a):

> [W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.

It is beyond argument that performance of only *one* of the three enumerated activities is patent infringement. It is well-established, in particular, that the *use* of a patented invention, without either manufacture or sale, is actionable. *See Aro Manufacturing Co.* v. *Convertible Top Replacement Co.,* 377 U.S. 476, 484, 141 USPQ 681, 685 (1964); *Coakwell* v. *United States,* 372 F.2d 508, 510, 153 USPQ 307, 308 (Ct. Cl. 1967). Thus, the patentee does not need to have *any* evidence of damage or lost sales to bring an infringement action.

Section 271(a) prohibits, on its face, any and all uses of a patented invention. Of course, as Judge Learned Hand observed in *Cabell* v. *Markham,* 148 F.2d 737, 739 (2d Cir.), *aff'd,* 326 U.S. 464 (1945):

> [I]t is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing: be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to ake a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.

Because Congress has never defined use, its meaning has become a matter of judicial interpretation. Although few cases discuss the question of whether a particular use constitutes an infringing use of a patented invention, they nevertheless convincingly lead to the conclusion that the word "use" in section 271(a) has never been taken to its utmost possible scope. *See, e.g., Pitcairn* v. *United States,* 547 F.2d 1106, 192 USPQ 612 (Ct. Cl. 1976), *cert. denied,* 434 U.S. 1051 (1978) (experimental use may be a defense to infringement); *United States* v. *Univis Lens Co.,* 316 U.S. 241 (1942) ("An incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it, * * *." *Id.* at 249); *General Electric Co.* v. *United States,* 572 F.2d 745, 198 USPQ 65 (Ct. Cl. 1978) ("[I]t can be properly assumed that as part of the bargain the seller of a device incorporating a patented combination * * * authorizes the buyer to continue to use the device so long as the latter can and does use the elements he purchased from the patentee or licensor." *Id.* at 784-85, 198 USPQ at 98).

Bolar argues that its intended use of flurazepam hcl is excepted from the use prohibition. It claims two grounds for exception: the first ground is based in a liberal interpretation of the traditional experimental use exception; the second ground is that public policy favors generic drugs and thus mandates the creation of a new exception in order to allow FDA required drug testing. We discuss these arguments *seriatim.*

B

The so-called experimental use defense to liability for infringement generally is recognized as originating in an opinion written by Supreme Court Justice Story while on circuit in Massachusetts. In *Whittemore* v. *Cutter,* 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600), Justice Story sought to justify a trial judge's instruction to a jury that an infringer must have an intent to use a patented invention for profit, stating:

> [I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

Despite skepticism, *see, e.g., Byam* v. *Bullard,* 4 F. Cas. 934 (C.C.D. Mass. 1852) (No. 2,262) (opinion by Justice Curtis), Justice Story's seminal statement evolved until, by 1861, the law was "well-settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee." *Peppenhausen* v. *Falke,* 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279). (For a detailed history and analysis of the experimental use exception, *see* Bee, *Experimental Use as an Act of Patent Infringement,* 39 J. Pat. Off. Soc'y 357 (1957).) Professor Robinson firmly entrenched the experimental use exception into the patent law when he wrote his famous treatise, W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890):

> § 898. No Act an Infringement unless it affects the Pecuniary Interests of the Owner of the Patented Invention.
>
> [T]he interest to be promoted by the wrongful employment of the invention must be hostile to the interest of the patentee. The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of a pecuniary character, and their value is capable of estimation like other property. Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. An unauthorized sale of the invention is always such an act. But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. *Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind.* But if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringe-

> ments of his patent. In reference to such employments of a patented invention the law is diligent to protect the patentee, and even experimental uses will be sometimes enjoined though no injury may have resulted admitting of positive redress. [Emphasis supplied, footnotes omitted.]

The Court of Claims, whose precedents bind us, on several occasions has considered the defense of experimental use. *See Ordnance Engineering Corp.* v. *United States,* 84 Ct. Cl. 1, 32 USPQ 614 (1936), *cert. denied,* 302 U.S. 708, 37 USPQ 842 (1937); *Chesterfield* v. *United States,* 159 F. Supp. 371, 116 USPQ 445 (Ct. Cl. 1958); *Douglas* v. *United States,* 181 USPQ 170 (Ct. Cl. Tr. Div. 1974), *aff'd,* 510 F.2d 364, 184 USPQ 613 (Ct. Cl.), *cert. denied,* 423 U.S. 825 (1975); *Pitcairn* v. *United States,* 547 F.2d 1106, 192 USPQ 612 (Ct. Cl. 1976), *cert. denied,* 434 U.S. 1051 (1978). Bolar concedes, as it must, that its intended use of flurazepam hcl does not fall within the "traditional limits" of the experimental use exception as established in these cases or those of other circuits. Its concession here is fatal. Despite Bolar's argument that its tests are "true scientific inquiries" to which a literal interpretation of the experimental use exception logically should extend, we hold the experimental use exception to be truly narrow, and we will not expand it under the present circumstances. Bolar's argument that the experimental use rule deserves a broad construction is not justified.

Pitcairn, the most persuasive of the Court of Claims cases concerning the experimental use defense, sets forth the law which must control the disposition of this case: "[t]ests, demonstrations, and experiments * * * [which] are in keeping with the legitimate business of the * * * [alleged infringer]" are infringements for which "[e]xperimental use is not a defense." 547 F.2d at 1125-1126, 192 USPQ at 625. We have carefully reviewed each of the other Court of Claims cases, and although they contain some loose language on which Bolar relies, they are unpersuasive. The *Ordnance Engineering* case provides no guidance concerning the boundaries of an appropriately applied experimental use rule other than flatly stating that a device must have been "built for experimental purposes." In *Chesterfield,* the court's flat declaration that "experimental use does not infringe" is pure *obiter dictum. See Pitcairn,* 547 F.2d at 1125, 192 USPQ at 625. *Douglas* has no precedential value here since the Court of Claims never affirmed the part of the trial judge's opinion dealing with experimental use; moreover, Trial Judge Cooper's well-reasoned analysis of the experimental use rule concluded that no case had permitted a pattern of systematic exploitation of a patented invention for the purpose of furthering the legitimate business interests of the infringer. The authority of Trial Judge Cooper's views rests on his reputation as a fine patent lawyer, and on their own intrinsic persuasiveness.

Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam hcl to derive FDA required test data is thus an infringement of the '053 patent. Bolar may intend to perform "experiments," but unlicensed experiments conducted with a view to the adaption of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use *de minimis.* It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned. We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry," when that inquiry has definite, cognizable, and not insubstantial commercial purposes.

C

Bolar argues that even if no *established* doctrine exists with which it can escape liability for patent infringement, public policy requires that we create a new exception to the use prohibition. Parties and *amici* seem to think, in particular, that we must resolve a conflict between the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-392 (1982), and the Patent Act of 1952, or at least the Acts' respective policies and purposes. We decline the opportunity here, however, the engage in legislative activity properly only for the Congress.

The new drug approval procedure which existed between 1938 and 1962 was relatively innocuous and had little impact on the development of pioneer prescription new drugs. Section 505 of the FDCA, ch. 675, 52 Stat. 1052 (1938), required the manufacturer of a pioneer new drug to submit to the FDA a New Drug Application (NDA) containing information concerning the safety of the drug. If the FDA did not disapprove the new drug within 60 days after it received the NDA, marketing could begin.

The provisions of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, caused a substantial increase in the time required for development and approval of a pioneer new drug. Beginning in 1962, the amended Section 505 (codified at 21 U.S.C. § 355 (1982)) required an NDA to contain proof of efficacy (effectiveness) as well as safety, and required the FDA affirmatively to approve the NDA rather than just to permit marketing by inaction. A recent study indicated that it now can take on average from 7 to 10 years for a pharmaceutical company to satisfy the current regulatory requirements. National Academy of Engineering, *The Competitive Status of the U. S. Pharmaceutical Industry* 79-80 (1983).

Because most FDA-required testing is done after a patent issues, the remaining effective life of patent protection assertedly may be as low as 7 years. *Id., citing* Statement of William M. Wardell to the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U. S. House of Representatives, Feb. 14, 1982, at 14. Litigation such as this is one example of how research-oriented pharmaceutical companies have sought to regain some of the earning time lost to regulatory entanglements. They gain for themselves, it is asserted, a *de facto* monopoly of upwards of 2 years by enjoining FDA-required testing of a generic drug until the patent on the drug's active ingredient expires.

Bolar argues that the patent laws are intended to grant to inventors only a limited 17-year property right to their inventions so that the public can enjoy the benefits of competition as soon as possible, consistent with the need to encourage invention. The FDCA, Bolar contends, was only intended to assure safe and effective drugs for the public, and not to extend a pharmaceutical company's monopoly for an indefinite and substantial period of time while the FDA considers whether to grant a pre-marketing clearance. Because the FDCA affected prevailing law, namely the Patent Act, Bolar argues that we should apply the patent laws to drugs differently.

Simply because a later enacted statute affects in some way an earlier enacted statute is poor reason to ask us to rewrite the earlier statute. Repeals by implication are not favored. *See, e.g., Mercantile National Bank* v. *Langdeau,* 371 U.S. 555, 565 (1963). Thus, "courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *Morton* v. *Mancari,* 417 U.S. 535, 551 (1974). There is no affirmative obligation on Congress to explain why it deems a particular enactment wise or necessary, or to demonstrate that it is aware of the consequences of its action. *See Harrison* v. *PPG Industries, Inc.,* 446 U.S. 578, 592 (1979). Rather, because "laws are presumed to be passed with deliberation, and with full knowledge of all existing ones on the same subject," T. Sedgwick, *The Interpretation and Construction of Statutory and Constitutional Law* 106 (2d ed. 1874), we must presume Congress was aware that the FDCA would affect the earning potentiality of a drug patent, and chose to permit it. Although arguably Title 21 and Title 35 are not laws on the "same subject," we note that during Congress' deliberations on the 1962 amendments to the FDCA, it considered the relationship and interaction of the patent laws with the drug laws. *See* S. Rep. No. 1744, 87th Cong., 2d Sess., *reprinted in* 1962 U.S. Code Cong. & Ad. News 2884, 2911-2915.

It is the role of Congress to maximize public welfare through legislation. Congress is well aware of the economic and societal problems which the parties debate here, and has before it legislation with respect to these issues. *See* H.R. 3605, 98th Cong., 1st Sess. (1983) ("Drug Price Competition Act of 1983") (amending 21 U.S.C. § 355(b) to allow faster marketing of new generic drugs equivalent to approved new drugs); S. 1306, 98th Cong., 1st Sess. (1983) ("Patent Term Restoration Act of 1983") (amending 35 U.S.C. § 155 to add to the patent grant a period of time equivalent to that lost due to regulatory delay), Cong. Rec. S. 6863 (daily ed. May 17, 1983), 26 Pat. Trademark & Copyright J. (BNA) 87-88 (May 26, 1983). No matter how persuasive the policy arguments are for or against these proposed bills, this court is not the proper forum in which to debate them. Where Congress has the clear power to enact legislation, our role is only to interpret and apply that legislation. "[I]t is not our job to apply laws that have not yet been written." *Sony Corp. of America* v. *Universal City Studios, Inc.*, 52 U.S.L.W. 4090, 4100, 220 USPQ 665, 684 (U.S. Jan. 17, 1984) (No. 81-1687). We will not rewrite the patent laws here.

IV

The district court refused to grant a permanent injunction against Bolar because it believed the law did not require that it find infringement of the '053 patent. Since we hold that there is infringement, Roche is entitled to a remedy. We are not in a position, however, to decide the form of that remedy.

Roche requested us, at first, to remand this case to the district court with instructions to enter a permanent injunction against infringement by Bolar. After the main briefs were filed, but before oral argument, the '053 patent expired. This case is not moot, however, because although the initially requested order no longer is necessary, other remedies can be fashioned to give Roche relief against Bolar's past infringement. Roche requests, for example, an order to confiscate and destroy the data which Bolar has generated during its infringing activity, *citing, Pfizer, Inc.* v. *International Rectifier Corp.,* 217 USPQ 157 (C.D. Cal. 1982) (granting an injunction of that nature to remedy infringement done in contempt of a court order).

Statute provides the basis for Roche's request for injunctive relief, 35 U.S.C. § 283:

> The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

Section 283, by its terms, clearly makes the issuance of an injunction discretionary: the court *"may grant"* relief *"in accordance with the principles of equity."* The trial court thus has considerable discretion in determining whether the facts of a situation require it to issue an injunction. The scope of relief, therefore, is not for us to decide at the first instance, nor is this the time or place for a discourse on the "principles of equity."

Whether an injunction should issue in *this* case, and of what form it should take, certainly depends on the equities of the case. Bolar, Roche, and *amici* Pharmaceutical Manufacturers Association and Generic Pharmaceutical Industry Association, each detail the "catastrophic" effect our decision for either party will have on the American public health system. It is true that it "is a principle of general application that courts, and especially courts of equity, may appropriately withhold their aid where the plaintiff is using the right asserted contrary to the public interest," *Morton Salt Co.* v. *Suppiger Co.,* 314 U.S. 488, 492 (1941), *reh'g denied,* 315 U.S. 826 (1942). Since "the standards of the public interest, not the requirements of private litigation, measure the propriety and need for injunctive relief in these cases,'' *Hecht Co.* v. *Bowles,* 321 U.S. 321, 331 (1944), *rev'g Brown* v. *Hecht Co.,* 137 F.2d 689 (D.C. Cir. 1943), we remand this case to the district court for further proceedings to consider what this interest is and what measures it calls for.

There are other aspects here that might make a tribunal reluctant to select, within the scope of its discretion, relief along the harsher side of the possible scale. The case clearly was regarded by both sides as a test. The good faith with which Bolar acted is undisputed, at least before us. Bolar says it did nothing clandestine, but notified Roche what it was going to do at all times before doing it, so Roche could act promptly to defend what it believed to be its rights. The case may be unlike *Pfizer, Inc., supra,* in that Bolar scrupulously obeyed all court orders while they were in effect, or so it says, whereas in *Pfizer, Inc.,* the infringer acted in defiance of court decrees. The destruction of material in *Pfizer, Inc.,* was ordered after everything milder had proved useless. If other measures can be made sufficient, one might well be reluctant to order destruction of the records of research and tests that may embody information that would contribute to the health and happiness of the human race. All this is, of course, for the district judge to consider so far as he finds the factual predicates established.

The actual infringing acts are said to have all occurred in the relatively brief period between vacation of the lower court's restraining order and the expiration of the patent. Counsel for Roche was candid in explaining that he pushed so hard for the harsh relief he did because he thought any money damages would have to be nominal. The correctness of this belief has not been briefed or argued, and we hesitate to state a firm position, but tentatively, at least, we are skeptical. It is clear that the economic injury to Roche is, or is threatened to be, substantial, even though the amount of material used in the tests was small. If the patent law precludes substantial damages, there exists a strange gap in the panoply (in its proper meaning, a suit of armor) of protection the patent statutes place around an aggrieved and injured patentee. The district judge, before getting into the issue of equitable relief, must determine if he can deal with the case by adequate money damages. If he can, the predicate for equitable relief of a harsh, or even a mild, character is gone.

Counsel are equally mistaken in their apparent belief that once infringement is established and adjudicated, an injunction must follow. In *Hecht Co.* v. *Bowles, supra,* the statute, unlike the one we have here, was seemingly mandatory by its language that once a violation was shown, an injunction *must* follow, and the D. C. Circuit had so held. But the circumstances made an injunction somewhat repugnant. Hecht Co., an unquestionably legitimate and long-established District of Columbia retailer, had got tangled up in the price control regulations of World War II, and its employees had in good faith unwittingly committed some violations. The situation was ironic in that the Hecht Co. had been a leader in extending the patriotic cooperation of the retail trade in application of the unpopular but necessary retail price controls, and had itself offered its own operation for study as illustrating the problems and how they could be solved.

After discovering some loopholes in the statute, in light of the legislative history, Justice Douglas continued at 329:

> We are dealing here with the requirements of equity practice with a background of several hundred years

> of history. Only the other day we stated that "An appeal to the equity jurisdiction conferred on federal district courts is an appeal to the sound discretion which guides the determinations of courts of equity." *Meredith* v. *Winter Haven,* 320 U.S. 228, 235. The historic injunctive process was designed to deter, not to punish. The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims. We do not believe that such a major departure from that long tradition as is here proposed should be lightly implied.

While two justices declined to join in the opinion, none expressed themselves in favor of affirming the D. C. Circuit. In short, if Congress wants the federal courts to issue injunctions without regard to historic equity principles, it is going to have to say so in explicit and even shameless language rarely if ever to be expected from a body itself made up very largely of American lawyers, having, probably, as much respect for traditional equity principles as do the courts. If an injunction was not mandatory in *Hecht Co.* v. *Bowles,* the more permissive statutory language here makes it *a fortiori* that an injunction is not mandatory now.

The application of historic equity principles to the case at bar is in the first instance for the district court.

V

Conclusion

The decision of the district court holding the '053 patent not infringed is reversed. The case is remanded with instructions to fashion an appropriate remedy. Each party to bear its own costs.

REVERSED AND REMANDED

Order of United States Court of Appeals for the Federal Circuit

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Appeal No. 84-560.

ON MOTION

ROCHE PRODUCTS, INC.,
Plaintiff-Appellant,
v.
BOLAR PHARMACEUTICAL CO., INC.,
Defendant-Appellee.

Before BALDWIN, *Circuit Judge.*

ORDER

Appellant's Second Motion To Expedite Appeal And To Shorten Briefing Schedule is *denied.*

When this case is ultimately heard and decided, and provided that appellant is successful, appellant can seek relief for the alleged infringement despite the expiration of the patent. Moreover, the appeal should not be expedited because appellant is not suffering any damage pending this appeal.

BY DIRECTION

/s/ GEORGE E. HUTCHINSON

George E. Hutchinson, Clerk

Nov. 4, 1983

Date

Order of United States Court of Appeals for the Federal Circuit

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Appeal No. 84-560.

ON MOTION

ROCHE PRODUCTS, INC.,
Appellant,
v.
BOLAR PHARMACEUTICAL CO., INC.,
Appellee.

Before BALDWIN, *Circuit Judge.*

ORDER

Appellant's Motion to Expedite Appeal and to Shorten Briefiing Schedule is *denied.*

BY DIRECTION
/s/ GEORGE E. HUTCHINSON
George E. Hutchinson, Clerk

October 24, 1983
Date

APPENDIX B

Opinion of United States District Court for the District of New Jersey

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Civil No. 83-2809

ROCHE PRODUCTS, INC.,
Plaintiff,
against

SST. CORP., BOLAR PHARMACEUTICAL CO.,
and ROBERT SCHULMAN, (sic)
Defendants.

Newark, New Jersey
September 2, 1983

BEFORE:

THE HONORABLE H. LEE SAROKIN, U.S.D.J.

APPEARANCES:

CRUMMY, DEL DEO, DOLAN & PURCELL, ESQS.
Attorneys for Plaintiff
BY: RALPH DEL DEO, ESQ.

ROBERT V. MARROW, ESQ.
Attorney for Defendants

WILLIAM SOKOL, C.S.R.
Official Court Reporter

THE COURT: This is an application for an Order to Show Cause and a Temporary Restraining Order.

Based upon the papers which have been submitted and the arguments which took place yesterday, the following facts appear to be undisputed:

The plaintiff, Roche Products, Inc., has continuously since 1970 marketed in this country dosage form pharmaceutical products under the registered trademark Dalmane. These products contain flurazepam hydrochloride as the active ingredient and are prescribed for relief of insomnia.

Dalmane brand pharmaceutical products have enjoyed marked and widespread acceptance by the medical profession. Plaintiff indicates that its current sales of Dalmane brand products excede (sic) forty million dollars.

Because of the exclusive rights provided by a United States patent, Roche Products is the sole lawful manufacturer and user of this product, and the sole supplier of pharmaceutical products containing flurazepam hydrochloride in the United States.

Roche's patent will expire on January 17th, 1984, less than five months from now.

The defendant Bolar is engaged primarily in the manufacture and sale of generic pharmaceutical products that sometime duplicate successful brand name drugs developed, manufactured and sold in dosage form by so-called research-oriented or pharmaceutical companies.

The defendant Robert Schulman (sic) is the founder and President of Bolar.

Defendants Bolar and Schulman (sic) admit that they have obtained and presently possess five kilograms of the raw material which is the subject of the patent, and that they intend and plan to soon commence using it to make dosage form capsules, to perform stability tests, dissolution tests, and clinical bio-availability studies, and to use such capsules, data and studies to seek approval from the Food and Drug Administration to commercially market dosage form capsules in competition with the Roche Products.

There is no dispute by defendant as to the validity of plaintiff's patent, and they assert that they have no intention of selling the product until the patent expires.

They seek, however, to be authorized to engage in sales the moment the patent expires.

There is little doubt that the action complained of, if committed in the first year of the patent, would constitute an infringement and would be enjoinable.

The defendants suggest, however, that the act should be viewed differently if they take place on the eve of the expiration of the patent and are preparatory to manufacture and sale once the patent expires when no infringement would or could exist.

The statute, however, makes no such exception. The monopoly granted is for the entire period. To hold otherwise would require a case by case determination of when such preparation could begin and what could be done in expectation of the expiration of the patent.

The Court sees little difference between testing and seeking approval in advance of the expiration date as opposed to other uses which would otherwise be considered infringement, even though no sale is contemplated.

In effect defendants argue that anything short of actual manufacture and sale should be permitted so as to allow for competition on the first day that the statute allows. Defendants contend that to do otherwise confers upon the patentee an extension of its monopoly, since competitors will be barred for a further extended period required to obtain the necessary approvals in order to commence production and sales.

That indeed may be the practical effect of the statute, but it does not warrant carving out an exception to the statute not granted by Congress. It would be a simple matter for Congress to declare that during the year prior to the expiration of a patent, others may use or make the patented item provided no sales take place until expiration.

The Congress, having failed to do so and having failed to provide any such exception, the Court should not do so.

No matter how minimal defendant's use of the patent may be, it should not be permitted to benefit from that illegal use even though it may not reap the benefits of such use until after the patent expires.

In addition to the presumption of irreparable harm which follows an infringement, the harm in this matter suffered by plaintiff is irreparable since defendant will, if permitted to continue, gain an advantage in the marketplace which they could not obtain but for the infringement.

The Court is concerned and recognizes that the injury will not actually occur until the patent has expired and competition is permitted, but the advantage gained by defendents has been gained by illegal means; therefore, the injury is occurring presently, although the effects may not be felt until after the patent expires and the monopoly ends.

The case is no different from a competitor manufacturing and stockpiling a patented item, but not selling it before the patent expires. Certainly there is irreparable injury even though it may not manifest itself until the future.

Additionally, the Court notes that monetary damages would be impossible to ascertain.

Therefore, the Court is satisfied that plaintiff has established a likelihood of success on the merits, and furthermore, that irreparable harm will occur if injunctive relief is not granted.

Furthermore, there is a great public interest in the protection of patented products. Assuming that when the patent expires the defendants may offer a comparable product at a reduced price, the advantage to the public at that time does not counterbalance the greater public interest in encouraging the research and development which patent protection fosters and encourages.

The Court would like to add one final note to this brief opinion.

As was stated prior to the argument, this case is assigned to Judge Debevoise and was heard by me on an emergency basis. I have ruled only that a Temporary Restraining Order should issue and, of course, I will provide for the issuance of the Order to Show Cause why a preliminary injunction should not be granted; however, in fairness and in deference to Judge Debevoise, my opinion in this matter should not be deemed to be the law of the case and Judge Debevoise should feel free to take a contrary position as to the law if he deems it appropriate, just as he would have had the right to do in considering a motion for preliminary injunction if he had decided the Temporary Restraining Order application in the first instance.

For those reasons the Court will grant the Temporary Restraining Order. It will be made returnable before Judge Debevoise on September 9th at 9 A.M., pursuant to the request of his Chambers.

There is a provision in the form of order for a bond. I don't know whether defendants require it. We are certainly dealing with a substantial company here.

What is your position on that?

Mr. Marrow: A minimal bond would be sufficient.

The Court: What do you suggest?

Mr. Marrow: A thousand dollars.

Mr. Del Deo: When will you need the thousand dollars?

The Court: I suppose we have to give you until Tuesday to file it.

Mr. Del Deo: File the bond?

The Court: Yes.

Mr. Del Deo: I can post my own check for a thousand dollars if you wish.

The Court: Why don't you do that. I think it is simpler than arranging for the bond. Why don't you post one thousand dollars security?

Is that satisfactory to counsel?

Mr. Marrow: Yes.

The Court: What about service? Can we consider service being effected through counsel?

Mr. Marrow: Yes, your Honor.

Are you referring to service of the moving papers?

The Court: And this Order to Show Cause, you will accept service?

Mr. Marrow: We acknowledge receiving it.

The Court: All right.

Mr. Del Deo: Your Honor—

The Court: Recognizing that this will be heard on Friday, when will defendants be able to file answering papers with Judge Debevoise?

Mr. Marrow: Monday is a holiday. I think we would need a few days next week.

The Court: Could you do it by, let's say, two o'clock on Wednesday, the 7th, we want him to have some time to read them.

If you have any problem you can call him, but I will insert that into the order.

Mr. Del Deo, do you wish to be heard?

Mr. Del Deo: Yes. What I would propose to do is give my personal check for a thousand dollars to the clerk, make it payable to the Clerk of the Court.

The Court: Yes.

Mr. Del Deo: And if it is all right with your Honor and with Mr. Marrow, I represent that the check is good and I will not stop a payment, but it would, I would just as soon if the clerk didn't cash it, but just hold it until Tuesday when I will replace it with a bond.

The Court: Or a check of your client. It may be more difficult—

Mr. Del Deo: I have my own check in my pocket. I can just make it out for a thousand dollars.

The Court: Is this really necessary? Should we bother at all with the thousand dollars?

Mr. Marrow: I will waive it, Judge.

The Court: Thank you.

Anything else?

I have provided that it shall be returnable, as I have already indicated, before Judge Debevois (sic) at nine A.M. on September 9.

The defendant shall file any answering papers by two o'clock on the 7th, which is Wednesday.

If there are any reply papers, which I would discourage because it won't give Judge Debevoise much time to read them, but I have provided that they be filed by September 8th, two o'clock.

I will give it to the clerk. Thank you, gentlemen.

Mr. Del Deo: We will bring the order in. We have a form of order and we will fill it out.

The Court: I have just done it. If you want to review it, I have just done it and signed it. Even though it was entitled "Motion," to me it is an order.

Why don't you and counsel review it? If you see any problems with it let me know. I will be here for a while. I have just signed it and filled it out.

Order of United States District Court for the District of New Jersey

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

Civil Action No. 83-2809 D

(Hon. Dickinson R. Debevoise)

CRUMMY, DEL DEO, DOLAN & PURCELL
A Professional Corporation
Gateway I
Newark, New Jersey 07102
(201) 622-2235
Attorneys for Plaintiff

ROCHE PRODUCTS INC.,
Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,
Defendant.

Defendants, Bolar Pharmaceutical Co., Inc. and Robert Shulman (sic) having moved for an Order, through their attorneys, Siegel & Barz, and Salon, Marrow, Dyckman & Trager, dismissing the Complaint in this action pursuant to Rules 12(b)(3) and 12(b)(6) of the Federal Rules of Civil Procedure, and the Court having considered Defendants' Motion and Supporting Memorandum and Affidavit, and the

Memorandum in Opposition of Roche Products Inc., and the Court having heard and considered argument this day by counsel for the parties, and the Court being advised that so much of defendants' motion to dismiss under Rule 12 (b)(6) has been withdrawn,

It is on this 26th day of September, 1983

Ordered that:

1. The caption of this action shall be Roche Products Inc. v. Bolar Pharmaceutical Co., Inc. by reason of the dismissal, without prejudice, of the action as to Robert Shulman (sic) by a Stipulation and Consent Order Pursuant to Rules 21 and 41(a) F.R.Civ.P. signed by counsel for the parties on September 16, 1983, and the entry on September 20, 1983 of a Consent Judgment as to SST Corp.;

2. Venue as to defendant Bolar Pharmaceutical Co., Inc. is improper in this judicial district;

3. To the extent that defendant's Motion seeks dismissal of the Complaint it is denied and the Court in the interest of justice directs that this action be transferred to the United States District Court for the Eastern District of New York which is a district in which this action could have been brought as to defendant Bolar Pharmaceutical Co., Inc. pursuant to 28 U.S.C. §1406(a);

4. The Clerk of this Court is directed to dispatch the papers in this action with all deliberate speed to the Clerk of the United States District Court for the Eastern District of New York and counsel for the parties are directed to

cooperate to the extent requested to do so by the Clerk of this Court to achieve speedy transmission and docketing of the action in the United States District Court for the Eastern District of New York.

5. The Temporary Restraining Order issued by the Honorable H. Lee Sarokin on September 2, 1983 which was continued in all respects to and including September 26, 1983 by a Stipulation and Consent Order of September 9, 1983 and which, pursuant to said Stipulation and Consent Order, could be extended to such other and different date as may be agreed to by counsel for the parties or as this Court shall otherwise direct, shall be and hereby is extended in all respects, pursuant to the consent of the parties heretofore given, to and including [Sept. 30, 1983 and thereafter if the parties consent thereto until—DRD] the date on which a Judge of the United States District Court for the Eastern District of New York hears the pending Motion of Roche Products Inc. for a Preliminary Injunction, which Motion has been briefed and was set for hearing before me on September 30, 1983.

Dated: Newark, New Jersey
September 26, 1983

So Ordered:

Dickinson R. Debevoise /s/

U.S.D.J.

Memorandum and Order of United States District Court for the Eastern District of New York

UNITED STATES DISTRICT COURT

Eastern District of New York

CV 83-4312

(Wexler, J.)

Roche Products, Inc.,
Plaintiff,
against
Bolar Pharmaceuticals Co., Inc.,
Defendant.

Appearances:

John C. Vassil, P.C.
Morgan, Finnegan, Pine, Foley & Lee, Esqs.
Attorneys for Plaintiff
345 Park Avenue
New York, New York 10154

Robert V. Marrow, Esq.
Salon, Marrow, Dyckman, & Trager, Esqs.
41 East 42nd Street
New York, New York 10017

Wexler, J.

This matter comes before the court as an action to permanently enjoin certain acts as threatened infringement of a patent. Suit was originally filed in U.S. District Court in New Jersey pursuant to 35 U.S.C. §§271 and 283, and under the grant of jurisdiction provided in 28 U.S.C. §1338. After District Judge H. Lee Sarokin issued a temporary restraining order on September 2, 1983, defendant was granted a change of venue pursuant to 28 U.S.C. §1406(a). District Judge Debevoise transferred venue to the Eastern District of New York for a hearing on the preliminary injunction, which was scheduled for October 5, 1983. At that time plaintiff moved to consolidate the hearing with a trial on the merits pursuant to Rule 65(a)(2) Fed.R.Civ. P. Defendant did not oppose and the court ordered the hearing consolidated with a trial on the merits.

Plaintiff Roche Products, Inc. (Roche) holds patent number 3,299,053 for flurazepam hydrochloride (flurazepam hcl). That compound is the active ingredient in a prescription sleeping pill manufactured by plaintiff under the brand name DALMANE. Plaintiff's seventeen year patent expires on January 17, 1984. Bolar Pharmaceutical Company (Bolar) is a generic drug company that duplicates drugs no longer under patent and sells the compounds to wholesale distributors. Bolar is in possession of five kilograms of flurazepam hcl, which it imported from a foreign manufacturer not subject to United States patent law. Plaintiff seeks to permanently enjoin defendant from performing required FDA experiments with the drug during the term of the patent.

There are no disputed facts in this case. There is no argument that the patent is for a pioneer invention and is valid and in force. Plaintiff's sales of DALMANE are in excess of $40,000,000 annually. There is no contention that Bolar will manufacture or sell flurazepam hcl before the patent expires, nor is it contended that Roche has authorized Bolar to make, use or sell the drug. Defendant acknowledges that it is in possession of five kilograms of imported flurazepam hcl and freely admits that it intends to form the compound into capsules and commence the testing and experiments necessary for a New Drug Application to the Food and Drug Administration (FDA) before the January 17, 1984 expiration date of the patent.

Title 35 U.S.C. §271(a) provides in pertinent part:

> [W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

Plaintiff argues that putting the drug through the FDA required testing and experimentation before the patent expires constitutes infringement under section 271(a), even if there is no intent to make, sell or otherwise realize a monetary gain until after January 17, 1984. Roche asserts that such action constitutes a *use* prohibited by the law. Bolar concedes that its tests do not fall under the infringement exception known as experimentation for philosophical, amusement, or curiosity purposes. It maintains that its testing does not constitute infringement use because it is *de minimis,* it does not by its nature infringe and no commercial value or profit will be realized before the patent on the drug expires. The defendant characterizes its activity as limited pre-expiration preparation for post-expiration entry into the market.

The question before the court is a very narrow one: does the limited use of a patented drug for experiments strictly related to FDA drug approval requirements during the last six months of the term of the patent constitute use prohibited by 35 U.S.C. §271(a)? The court holds that it does not.

An underlying issue in this case is the procedure for getting FDA approval, without which a drug cannot be marketed. Bolar asserts that it will take two years to amass required data and obtain approval, in effect delaying entry into the market and extending the patent *de facto* for the same period. Roche claims that it is entitled to that delay in competition, but can point to no legal support. It can only be observed that patent protection is contained in a single, general body of law meant to apply to inventions of every sort, not only drug compounds. The delaying regulations of the FDA could hardly be considered a part of the monopoly benefits Congress sought to bestow. *See* 35 U.S.C. §154. Viewed from this vantage, what is at stake is a post-expiration competitive benefit for Bolar at Roche's expense.

The plaintiff urges the adoption of the reasoning and holding of the recent case of *Pfizer, Inc.* v. *International Rectifier Corp.*, 217 U.S.P.Q. 157 (C.D. Calif. 1982). There the district court in California had issued a 1980 injunction against defendant's activities as infringement of plaintiff's drug patent. Before that court were two years of post-injunction product testing and development involving at least 400 kilograms of the drug and apparently profitable overseas manufacture and sale. The defendant in *Pfizer* was clearly doing more, for a longer period of time than Bolar intends to do here. More significantly, in *Pfizer* the defendant was reaping commercial value in defiance of a court injunction. The substantial and long term acts in violation of an injunction present in *Pfizer* are not present in the case at bar. Consequently, this court declines to make a wholesale adoption of the California court's reasoning and holding.

The *Pfizer* court, although it draws on the analysis and reasoning of cases from all the circuits, is bound by the

Ninth Circuit Court of Appeals' reading of the law, which strictly limits the experimental use exception to purposes of amusement and philosophical gratification. *Spray Refrigeration Co. v. Sea Spray Fishing, Inc.*, 322 F.2d 34 (9th Cir. 1963). This court, of course, is not bound by the Ninth Circuit, and although plaintiff advocates their analysis, the court instead turns to the line of reasoning followed by the Court of Appeals for the Second Circuit.

Bolar's experimentation cannot be classified as merely for amusement or philosophical gratification. At the same time, it cannot be connected with any act of competition or profit during the term of the patent in either domestic or foreign markets. Its experimentation is commercial preparation of a nonproduction nature for post-expiration competition. In analagous cases this has been held a noninfringing use. In *Arko Agate v. Master Marble Co.*, 18 F. Supp. 305 (N.D.W.Va. 1937), the experimentation with a marble manufacturing device covered by plaintiff's patent prior to going into production was held not an infringing use. The use of the apparatus was clearly a commercial test, yet in the absence of any profit from the activity, the court found no infringement. Similarly, in *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223 (S.D.N.Y. 1944), *aff'd* 156 F.2d 29 (2d Cir. 1946), building and commercial testing of a device without commercial manufacture or sale was deemed not to be an infringing use. Again, in *Chesterfield v. United States*, 159 F. Supp. 371 (Ct. Cl. 1958), no infringement was found where the federal government conducted tests and experiments. Citing *Bosnack Mack Co. v. Underwood*, 73 F. 206 (C.C. 1896), the Court of Claims stated flatly, "Experimental use does not infringe." 159 F. Supp. at 375. Bolar's FDA-mandated testing clearly falls in line with the sort of commercial experiments without profit, manufacture, or sale during the patent term that the Court of Appeals holds is non-infringing.

To find infringing use there must be a benefit at the expense of the patent. In *Kaz Manufacturing Co., Inc.* v. *Chesebrough-Pond's, Inc.*, 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd* 317 F.2d 679 (2d Cir. 1963), the court declared use to be "the commercially valuable use of which patentee could or would avail himself." The court held that as long as defendant was not helping himself to a benefit of a type secured by the patent, there was no infringement. Similarly, post-expiration advantage would not be a value secured by the patent. Furthermore, Bolar's activity cannot be connected with any benefit during the term of the patent.

In a like vein, the *de minimis* doctrine would seem to apply. Stated more fully, the law does not concern itself with small matters. In *Maxon Premix Burner Co.* v. *Eclipse Fuel Engineering Co.*, 471 F.2d 308 (7th Cir. 1972), the Seventh Circuit Court of Appeals held the experimental construction of a prototype even paired with a sale was *de minimis* and insufficient to support an action for threatened infringement. In the case at bar, Roche can point to no substantial loss that would stem from Bolar's studies. The only harm Roche can point to is a violation of the principle of its monopoly.

A court should be cautious in applying the equitable remedy of a permanent injunction in patent cases, *American Safety Device Co.* v. *Kurland Chemical Co.*, 68 F.2d 734 (2d Cir. 1934), particularly where, as here, there remains little more than three months to the term of the patent. This is doubly true where the case involves only a threatened infringement.

More importanly, the court cannot find a basis for holding that Bolar's limited experimental use of flurazepam hcl would constitute infringement. First, Bolar realizes no benefit during the term of the patent; its activities are in no way connected wilth current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the patent law. This court will not act to protect a right or benefit that is without legal basis. Third, Roche can point to no substantial harm it will suffer from Bolar's FDA studies before the patent expires. Bolar's threatened activity is at best *de minimis* and will not support an action for infringement.

If, however, it develops that Roche suffers substantial harm or loss during the patent's term, it still has available to it action at law for damages against Bolar.

Accordingly, no permanent injunction will issue and the temporary restraining order is dissolved. Parties will bear their own costs.

So ORDERED.

/s/ LEONARD D. WEXLER

LEONARD D. WEXLER, U.S.D.J.

Dated: Brooklyn, New York
October 11, 1983

APPENDIX C

Judgment of United States District Court for the Eastern District of New York

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF NEW YORK

CV 83 4312 (LDW)

ROCHE PRODUCTS, INC.,

Plaintiff,

against

BOLAR PHARMACEUTICALS CO., INC.,

Defendant.

A memorandum and order of Honorable Leonard D. Wexler, United States District Judge, having been filed on October 13, 1983, denying plaintiff's motion for a permanent injunction, dissolving the temporary restraining order, and dismissing the complaint without costs, it is

ORDERED and ADJUDGED that the plaintiff take nothing of the defendant; that plaintiff's motion for a permanent injunction is denied; that the temporary restraining order is dissolved; that the complaint is dismissed; and that the parties are to bear their own costs.

/s/ ROBERT C. HEINEMANN

Robert C. Heinemann
Clerk of Court

Dated: Brooklyn, New York
October 13, 1983

Judgment of United States Court of Appeals for the Federal Circuit

UNITED STATES COURT OF APPEALS

FOR THE FEDERAL CIRCUIT

No. 84-560, 83-4312 (LDW)

ROCHE PRODUCTS, INC.,
Appellant,
v.
BOLAR PHARMACEUTICAL CO., INC.,
Appellee.

ON APPEAL from the U. S. District Court for the Eastern District of New York

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED: REVERSED AND REMANDED, with instructions to fashion an appropriate remedy.

ENTERED BY ORDER OF THE COURT

George E. Hutchinson, Clerk

/s/ GEORGE E. HUTCHINSON
Clerk

DATED April 23, 1984

ISSUED AS A MANDATE:
May 15, 1984

APPENDIX D

U.S. Constitution

Section 8, Clause 8. Patents and copyrights

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;

Title 21 USC § 355

§ 355. New drugs—Necessity of effective approval of application

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

Filing application; contents

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

Title 35 USC § 154

§ 154. Contents and term of patent

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, of the right to exclude others from making, using, or selling the invention throughout the United States, referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof. July 19, 1952, c. 950, § 1, 66 Stat. 804.

Title 35 USC § 271

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

Title 35 USC § 283

§ 283. Injunction

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable. July 19, 1952, c. 950, § 1, 66 Stat. 812.

APPENDIX E

Article in Volume 224 No. 4653 of *Science*, published by American Association for the Advancement of Science

PATENTS ENCROACHING ON RESEARCH FREEDOM

A tradition of disregarding patent infringement when it involves experimental use of an invention may be eroding for biologists

Some two dozen researchers at universities, companies, and government laboratories recently received letters from Johnson & Johnson warning them that the use in research of particular cells that produce monoclonal antibodies may infringe the company's patent rights. The letter raises the tricky question of the extent to which patent law can be used to restrict research uses of patented products and processes.

A similar issue was raised recently in a court decision concerning clinical testing of a patented drug. The U.S. Court of Appeals for the Federal Circuit, which now hears all patent appeals, ruled that Bolar Pharmaceutical, a generic drug manufacturer, broke the law by testing its version of a drug made by Roche Products before Roche's patent had expired. Some patent attorneys are concerned that, if the ruling is interpreted broadly, it could be used to restrict a variety of research activities.

Although Johnson & Johnson's warnings and the contest between Roche and Bolar are not directly related, they both address an area of patent law that is in a considerable state of flux. The statutes spell out in plain language how a patent grants a 17-year monopoly to an inventor, prohibiting others from making, using, or selling the invention.

However, a tradition that began in the early 19th century has usually exempted experimental use of an invention from being construed as infringement. The issue at stake now is how to define when experimental use of patented technology becomes commercially threatening to an inventor and therefore no longer is entitled to that exemption. Some resolution of this ambiguity will be vital to the biotechnology industry, which is so heavily dependent on basic and near-basic research activities.

The contest between Roche and Bolar has been closely watched in the pharmaceutical industry. Early in 1983 Bolar began an effort to get federal approval to market flurazepam hydrochloride, the active ingredient in Roche's highly successful sleeping pill, whose trademark is Dalmane. Although the safety of this drug already was established, the Food and Drug Administration requires a generic drug manufacturer to prove it can meet the same standards. However, if the generic manufacturer is forced to wait until a drug's patent expires before such tests begin, the original manufacturer effectively gains a considerable extension on the patent's lifetime. [Legislation now being drafted by Representative Henry Waxman (D-Calif.) would resolve some of these problems (*Science,* 27 April, p. 369).]

Roche's patent for Dalmane expired on 17 January 1984, but Bolar began clinical trials long before that date. Roche brought a patent infringement suit against Bolar in July 1983. In October, the U.S. District Court in the Eastern District of New York ruled in Bolar's favor, but on 23 April 1984 that ruling was reversed on appeal. Bolar currently is planning to petition the Supreme Court to review the case, says attorney Robert Marrow, who represents the company.

"From the scientific point of view, the real threat [in the appeal court's decision] is it effectively prohibits any experiments with a patented product if it tends toward commercial development," Morrow says. "This is a far-reaching opinion that [could] negate the experimental use exception, unless it's for pure amusement."

Morrow's interpretation is something of a worst-case reading of the opinion handed down by Judge Philip Nichols, Jr. But other attorneys are also speculating about how far his opinion goes in this direction. "The experimental use exception is not gutted," says Jorge Goldstein, a patent attorney for a Washington, D.C. firm that represents a broad spectrum of corporate clients (but with no direct stake in the Roche-Bolar contest). "But for a company to argue that it's 'just doing research,' won't fly if it has a substantial commercial purpose."

The ruling "may not be a serious inroad" on the experimental exception to patents, says James Weseman, a patent attorney with a San Francisco law firm with biotechnology company clients. But certain passages in Judge Nichols' opinion where he uses "expansive language to define experimental use" are worrying, Weseman says.

For example, Nichols wrote: "Bolar's intended use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry [and] is thus an infringement. . . . We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."

"The biotechnology industry is sensitive to anything that affects what they do best—research," Weseman continues. "If case law develops so that even in the earliest stages companies must avoid patent infringement, it will really restrict their abilities and stultify their research. There's plenty to worry about."

The recent actions by Johnson & Johnson could be another step toward restricting use of patents that is a cause for more worry. Johnson & Johnson patent attorney Geoffrey Dellenbaugh has been sending out letters to researchers warning against the use of particular monoclonal antibody-producing hybridomas, which the company has deposited with the American Type Culture Collection (ATCC) in the course of obtaining patents. "The fact that you have obtained samples of these hybridomas from the ATCC in no way grants you any right or license under our patents in the United States or other countries," one of the letters, sent to a researcher at the National Institutes of Health (NIH), says. "Your use of these hybridoma samples may constitute infringement of one or more of these patents, regardless of whether the thus-produced antibody is subsequently used or sold."

About two dozen researchers from universities, companies, and government research institutions including NIH are involved so far. The letters were sent out because of the concern that "people might use the cells in a way that infringes the patent and deprives us of sales of antibodies," explains Dellenbaugh. The cells can be obtained from ATCC at a nominal cost, whereas Johnson & Johnson's subsidiary, Ortho Diagnostics, is marketing the antibodies (for research and diagnostic purposes) to make a profit. The company quite naturally would like to protect its commercial interests and develop a market for its patented monoclonal antibodies. Researchers would like to use those antibodies (some of them are to T cells, which are part of the immune system). And scientists with the right know-how undoubtedly can make the antibodies—from the company's cell lines, obtained perfectly legally from ATCC—more cheaply than they can be bought.

"The reason we wrote those letters was to inform people of the possible legal consequences. We intend, in appropriate circumstances, to protect our rights," Dellenbaugh says. The question, as with the Roche versus Bolar ruling, is "How far does that extend?" he adds. "If someone made an improvement that used your patented invention and uses that for commercial purposes—whether they're in a university or not—that is infringement of your patent."

"We've had correspondence with J&J, but have not resolved the issue," says NIH patent attorney Thomas Ferris. "We don't consider it infringement [for researchers to use cell lines] as long as it is experimental." In letters to Dellenbaugh, NIH patent attorneys have said, "[W]e will cooperate in your attempt to enforce your patent rights while at the same time recognizing that the interests of the research program of the [NIH] must be paramount, if it should prove to be more practicable to purchase hybridomas from ATCC for research purposes. We suggest that you promote your own sale of hybridomas by publicizing their availability to the NIH research community."

Dellenbaugh replied that each case should be considered individually, and that a determination should not rest "simply on whether the use is 'experimental.' . . . Since [there is] clear economic harm to Ortho, the rationale sometimes used for excepting experimental use from infringement should not apply."

NIH recently convened a meeting of its internal patent board, a group that includes patent attorneys and representatives from the various institutes, to consider the policy implications of the letters and has considered making recommendations on these issues to the Department of Health and Human Services. Currently, NIH is telling researchers "to go along the way they are."

Though Johnson & Johnson is not planning legal action to enforce its patent rights, according to Dellenbaugh, "If we decided an example needs to be made of an egregious infringement, we might do it." Hence, Ferris says, no matter what policy is laid down, such issues "ultimately can only be resolved in the courts."—JEFFREY L. FOX

Office - Supreme Court. U.S.
FILED
AUG 31 1984
ALEXANDER L. STEVAS,
CLERK

2

No. 84-130

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

BOLAR PHARMACEUTICAL CO., INC.,
Petitioner,
v.
ROCHE PRODUCTS, INC.,
Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF AMICUS CURIAE OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

IN SUPPORT OF AFFIRMANCE

PETER BARTON HUTT
(Counsel of Record)
ELLEN J. FLANNERY
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
P.O. Box 7566
Washington, D.C. 20044
(202) 662-5522
Attorneys for Amicus Curiae Pharmaceutical Manufacturers Association

Of Counsel:
BRUCE J. BRENNAN
Vice President and General Counsel
Pharmaceutical Manufacturers Association
1100 Fifteenth Street, N.W.
Washington, D.C. 20005

August 31, 1984

PRESS OF BYRON S. ADAMS, WASHINGTON, D.C. (202) 347-8203

BEST AVAILABLE COPY

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTEREST OF AMICUS CURIAE 1

QUESTIONS PRESENTED 2

COUNTERSTATEMENT OF THE CASE 3

REASONS FOR DENYING THE WRIT 5

I. The Federal Circuit's Decision Correctly Provides Strong Protection For Drug Patents, Consistent With The Constitution And Patent Law, At A Time When FDA Requirements For Approval Of New Drugs Have Substantially Reduced The Effective Patent Life Of These Products 5

  A. It Takes 7-13 Years During the Patent Term To Satisfy FDA Premarketing Requirements for Testing and Approval of Pioneer Prescription New Drugs 6

  B. The Cost of Developing a Pioneer Prescription New Drug Has Escalated 8

  C. The Effective Patent Life of a Pioneer Prescription New Drug Has Been Cut in Half as a Result of FDA Regulatory Requirements 11

II. The Unlicensed Use Of Patented Drugs For The Purpose Of Developing Generic Drug Products And Conducting The Tests Required For FDA Approval Directly Injures The Patent Holder 13

III. The Federal Circuit Properly Declined To Create For Generic Drug Companies A New Exception To The Use Prohibition Which Would Further Erode Patent Protection For Pioneer New Drugs And Would Thus Be Contrary To The Patent Law And Harm Public Health In The United States 15

CONCLUSION 18

APPENDICES:

Page

Appendix A: Real Research and Development Costs Per Pioneer Prescription New Drug, 1962-1972 ...... 1a

Appendix B: Trends in Average Effective Patent Life of Pioneer Prescription New Drugs, 1966-1981 ..... 2a

TABLE OF AUTHORITIES

CASES: Page

Dawson Chemical Co. v. *Rohm & Haas Co.*, 448 U.S. 176 (1979) 15

Eli Lilly and Co. v. *Premo Pharmaceutical Laboratories, Inc.*, 360 F.2d 120 (3d Cir.), *cert. denied*, 449 U.S. 104 (1980) 15

Weinberger v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) 6

CONSTITUTION, STATUTES, BILLS, AND REGULATIONS:

United States Constitution, Article I, Section 8

21 U.S.C. § 355 .... 4, 5

35 U.S.C. § 271(a) 13

42 U.S.C. § 2183 14

42 U.S.C. § 7404 14

Drug Amendments of 1962, 76 Stat. 780 (1962) 3, 5

Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended 5

Patent Amendments of 1980, 94 Stat. 3015 (1980) 16

21 Code of Federal Regulations:

Part 10 6

Part 50 7

Part 56 7

Part 58 6

Part 312 7

Part 314 .... 7, 8

Part 320 8

44 Federal Register 20796 (April 6, 1979) 6

45 Federal Register 41705 (June 20, 1980) 6

46 Federal Register 24693 (May 1, 1981) 6

H.R. 6245, 87th Cong., 1st Sess. (1961) 14

H.R. 915, 97th Cong., 1st Sess. (1981) 14

S. 1552, 87th Cong., 1st Sess. (1961) 14

S. 1297, 88th Cong., 1st Sess. (1963) 14

Page

S. 2287, 93d Cong., 1st Sess. (1973) 14

OTHER AUTHORITIES:

"Administered Prices — Drugs," S. Rep. No. 448, 87th Cong., 1st Sess (1961) 14

Baily, *Research and Development Costs and Returns: The U.S. Pharmaceutical Industry*, 80 J. Pol. Economy 78 (January/February 1972) 10

Clymer, "The Changing Costs and Risks of Pharmaceutical Innovation," in J.D. Cooper, ed., *Economics of Drug Innovation* 123 (1969) 10

Clymer, "The Economics of Drug Innovation," in Parnowski & Darrach, ed., *The Development and Control of New Drug Products* 109 (1972) 9

"Drug Industry Antitrust Act," Hearings before the Antitrust Subcommittee of the Committee on the Judiciary, House of Representatives, 87th Cong., 2d Sess. (1962) 14

"Drug Industry Antitrust Act," Hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, United States Senate, 87th Cong., 1st Sess., Parts 1-5 (1961) 14

Eisman & Wardell, "The Decline in Effective Patent Life of New Drugs," *Research Management* 18 (January 1981) 13

Fries, "Aging, Natural Death, and the Comprehension of Morbidity," 303 *New Eng. J. Med.* 130, 132 (July 17, 1980) 16

General Accounting Office, *Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry*, Report No. B-164031(2) (1968) 16

Hansen, "The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effects of Proposed Regulatory Changes," in R.I. Chien, *Issues in Pharmaceutical Economics* 151 (1979) 10

Table of Authorities Continued

Page

Mansfield, Panel Discussion, in J.D. Cooper, ed., *Economics of Drug Innovation* 149 (1969) 9

National Academy of Engineering, *The Competitive Status of the U.S. Pharmaceutical Industry* (1983) .11, 16

National Center for Health Statistics, *Monthly Vital Statistics Reports — Annual Summary of Births, Deaths, Marriage and Divorce: United States, 1980*, Vol. 29, No. 13 (1981) 16

National Center for Health Statistics, *Vital Statistics of the United States, 1960*, Vol. 2, Pt. A (1961) 17

Office of Technology Assessment, *Patent Term Extension and the Pharmaceutical Industry* (1981) 16

"Patent Term Extension and Pharmaceutical Innovation," Hearing before the Subcommittee on Investigations and Oversight of the Committee of Science and Technology, House of Representatives, 97th Cong., 2d Sess. (1982) 13

Pracon, Inc., *The Effective Patent Life of Pharmaceutical Products: Trends and Implications* (1978) 12

Sarett, "Impact of Regulations on Industrial R&D: FDA Regulations and Their Influence on the Future of R&D," *Research Management* 18 (March 1974) .. 9

Schnee, "Development Costs, Determinants and Overruns," *Journal of Business* 347 (July 1972) 9

Schwartzman, *Innovation in the Pharmaceutical Industry* (1976) 9, 12

Statman, "The Effect of Patent Expiration on the Market Position of Drugs," in R.B. Helms, ed., *Drugs and Health: Economic Issues and Policy Objectives* 140 (1980) and in *Managerial and Decision Economics* 61 (June 1981) 12

"The Food and Drug Administration's Process for Approving New Drugs," Report by the Subcommittee on Science and Technology, House of Representatives, 96th Cong., 2d Sess. (1980) 6

Table of Authorities Continued

Page

U.S. Department of Health and Human Services, *Morbidity and Mortality Weekly Report — Annual Summary, 1981*, Vol. 29, No. 56 (September 1981) ... 17

U.S. Department of Health, Education and Welfare, *Morbidity and Mortality Weekly Report — Annual Supplement, 1961*, Vol. 29, No. 54 (September 1961) 17

Wardell, "The History of Drug Discovery, Development and Regulation," in R.I. Chien, ed., *Issues in Pharmaceutical Economics* 10 (1979) 8

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

No. 84-130

BOLAR PHARMACEUTICAL CO., INC.,
Petitioner,
v.
ROCHE PRODUCTS, INC.,
Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF AMICUS CURIAE OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

INTEREST OF AMICUS CURIAE

This brief *amicus curiae* in opposition to the petition for writ of certiorari is submitted on behalf of the Pharmaceutical Manufacturers Association (PMA).[1] PMA is a voluntary nonprofit association of 135 companies that are responsible for discovering, developing, manufacturing, obtaining Food and Drug Administration (FDA) approval of, and selling almost all of the pioneer prescription new drugs in this country.[2] One of the most important incentives in the development of these life-saving products is the United States patent system. Without patent protection, the enormous investment necessary for the development of a pioneer new drug would not be feasible.

---

[1] Letters from counsel for the parties consenting to the filing of this brief are being filed with the Clerk.

[2] In contrast, the members of the Generic Pharmaceutical Industry Association (GPIA), which is submitting a brief *amicus curiae* in support of the petition for writ of certiorari in this case, only rarely conduct research on, or otherwise develop, pioneer new drugs.

This case strikes at the heart of patent protection. Petitioner Bolar Pharmaceutical Co., Inc. (Bolar), a generic drug company that does almost no developmental research of its own, asserts the right to encroach upon the patent of Roche Products, Inc. (Roche), in order to satisfy FDA regulatory requirements for marketing a generic drug. PMA believes that the decision of the United States Court of Appeals for the Federal Circuit, which petitioner Bolar asks this Court to review, is clearly correct in holding that the unlicensed use of a patented drug for development, testing, and other purposes in order to satisfy regulatory requirements is an illegal infringement, and the decision does not present any issue that warrants further review by this Court.

QUESTIONS PRESENTED

1. Is the unlicensed use of a patented drug, while the patent remains valid and unexpired, prohibited by the patent law where the user is conducting tests and experiments to adapt the patented invention to the user's business and to satisfy FDA regulatory requirements for marketing the product?

2. Can a generic drug company encroach upon the valid patent of a research-intensive pharmaceutical company and reduce the effective patent life by about two years by using the patented drug in order to satisfy FDA premarketing requirements prior to expiration of the patent term, where the effective patent life of the pioneer new drug is reduced by an average of seven to thirteen years while the research-oriented company conducted investigations to satisfy FDA premarketing requirements?

COUNTERSTATEMENT OF THE CASE

There are two categories of prescription new drugs marketed in the United States. The first category consists of the pioneer new drugs, developed by research-intensive pharmaceutical companies. It requires many years and millions of dollars to develop new pharmaceutical products and then to conduct the safety and effectiveness testing that is necessary to obtain FDA approval for marketing these drugs. The second category consists of generic copies of those pioneer new drugs. These copies require only a modest investment for marketing by generic drug companies like petitioner Bolar, which conduct no innovative new pharmaceutical research or development for these products.

Since enactment of the stringent regulatory requirements in the Drug Amendments of 1962,[3] the time required to develop and obtain FDA approval for a pioneer prescription new drug has increased from about 2 years to about 7-13 years. The cost of financing this process of innovation and regulatory approval for an average pioneer new drug has correspondingly escalated in constant dollars from about $6 million prior to 1962 to $44 million in 1972 and a great deal more today. The time needed to satisfy these requirements, moreover, inevitably is taken out of the innovator's patent life. Because a patent usually is filed and granted in the early years of drug innovation, every year required for testing and governmental approval reduces the effective patent life at the front end. A pioneer new drug approved for marketing by FDA today can be expected, as a result, to have an effective patent life of about half of the 17 years intended by Congress.

In contrast with this lengthy process that is required of the pioneer manufacturer, the generic manufacturer need spend only about 2 years to copy the pioneer drug, do the testing required, and obtain the expedited FDA approval that exists for these products.[4] Thus, generic manufacturers have an enormous competitive advantage in copying the results of the research of pioneer manufacturers, with little investment and no risk.

---

[3] 76 Stat. 780 (1962) (amending 21 U.S.C. § 355).

[4] Petition for writ of certiorari, p. 4.

In this case, Bolar used Roche's patented drug, while the patent remained valid and unexpired, to begin to perform the research required to formulate its own generic drug product.[5] Bolar also used the patented invention to begin to develop the data that must be submitted to FDA in order to obtain approval to market the generic drug product. Bolar asserts that it had the right to encroach upon Roche's patent, without authorization from Roche, for purposes of developing and testing its competitive drug product.

The Court of Appeals for the Federal Circuit held that this use by Bolar was an infringement of Roche's patent.[6] It is obvious that unlicensed use of a patented drug, in violation of a valid unexpired patent, directly injures the patent holder by depriving the patent holder of profits from the sale or licensing of the drug to other drug manufacturers, during the patent term, for whatever development and testing is necessary to satisfy regulatory requirements. The Court of Appeals decision prohibited Bolar from obtaining the benefits of such a sale or license arrangement without authorization from Roche.

Bolar also argued that it should be permitted to encroach upon the unexpired patent to develop its competitive product and to perform the tests required for FDA approval of the product so that it could compete with the patented product immediately upon expiration of the patent. According to Bolar, any other result would extend for 2 years after patent expiration the monopoly of patent holders in the pharmaceutical industry. The Court of Appeals rejected this argument. The Court recognized that Bolar was asking it to apply the patent laws to drugs differently than to other products. Because the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) requires Bolar to conduct testing and obtain FDA approval before it can market its generic drug product, Bolar wanted the Court to allow it to encroach upon a valid and unexpired patent for that two-year period. The Court of Appeals refused to allow this commercially significant encroachment in the guise of an expanded "experimental use" defense to liability for infringement.

---

[5] Petition for writ of certiorari, p. 3.

[6] 733 F.2d 858 (Fed. Cir. 1984) (Appendix A to Petition for writ of certiorari).

REASONS FOR DENYING THE WRIT

The Federal Circuit's decision, which carefully reviewed and unanimously rejected petitioner's legal and factual claims, rests on settled patent law principles, is clearly correct, and does not present any issue that warrants further review by this Court.

I. The Federal Circuit's Decision Correctly Provides Strong Protection For Drug Patents, Consistent With The Constitution And Patent Law, At A Time When FDA Requirements For Approval Of New Drugs Have Substantially Reduced The Effective Patent Life Of These Products.

Section 505 of the Federal Food, Drug, and Cosmetic Act of 1938[7] required the manufacturer of a pioneer new drug to submit to FDA a new drug application (NDA) containing information relating to the safety of the drug. If FDA did not disapprove the drug within 60 days after receiving the NDA, marketing could begin.

Congress enacted the Drug Amendments of 1962[8] to strengthen Section 505[9] in light of the thalidomide disaster. Beginning in 1962, an NDA was required to contain data proving effectiveness as well as safety. FDA was also required affirmatively to approve the NDA rather than just to permit marketing by inaction.

The new drug requirements that existed between 1938 and 1962 were relatively innocuous and had little impact on the development of pioneer prescription new drugs. The provisions of the Drug Amendments of 1962, however, have resulted in a substantial increase in the time required for development and approval of a pioneer new drug. Thus, FDA regulatory requirements have substantially reduced the effective patent life of pioneer new drug products.[10]

---

[7] 52 Stat. 1040 (1938).

[8] 76 Stat. 780 (1962).

[9] Section 505, as amended, is codified at 21 U.S.C. § 355.

A. It Takes 7-13 Years During the Patent Term To Satisfy FDA Premarketing Requirements for Testing and Approval of Pioneer Prescription New Drugs.

As demonstrated in a 1980 Report by the House Subcommittee on Science, Research and Technology, FDA regulatory requirements impact upon the drug development process from the moment a new chemical entity is synthesized until final FDA approval of an NDA.[11] That process is divided into three major stages: preclinical research, clinical investigation, and NDA approval.

Preclinical Research. Before clinical investigation of a new chemical entity may begin, sufficient animal testing data must exist to justify use of the chemical in humans.[12] Innovators must also undertake substantial research on the chemical, pharmacologic, and toxicologic properties of the chemical during preclinical research. The FDA requirements for good laboratory practices (GLP) in conducting preclinical research for a new drug have substantially added to both the cost and the time for this type of research. Accordingly, it is not surprising that the House Subcommittee Report found that preclinical research can take 1 to 4 years to complete.[13]

---

[10] The "effective patent life" of a drug is measured from the date of FDA approval of the NDA to the date of expiration of the patent.

[11] "The Food and Drug Administration's Process for Approving New Drugs," Report by the Subcommittee on Science, Research, and Technology, Committee on Science and Technology, House of Representatives, 96th Cong., 2d Sess. (1980) (hereafter "House Subcommittee Report"). *See also* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973).

[12] Formal guidelines are issued by the FDA pursuant to 21 C.F.R. § 10.90(b). *See, e.g.*, 44 Fed. Reg. 20796 (April 6, 1979); 45 Fed. Reg. 41705 (June 20, 1980); 46 Fed. Reg. 24693 (May 1, 1981); 21 C.F.R. Part 58.

Clinical Investigation. Once adequate preclinical research is completed, innovators may submit the results of this research to FDA in order to obtain permission to begin clinical investigation of the investigational new drug (IND) in humans. Lengthy and detailed regulations and guidelines establish what FDA demands for evidence of safety and effectiveness of a pioneer new drug.[14] The House Subcommittee Report found that it takes about 4 to 6 years to conduct this IND research in accordance with FDA requirements in order to demonstrate that the drug is both safe and effective.

NDA Approval. After the FDA requirements for preclinical research and clinical investigation are completed, an NDA is submitted to FDA to obtain approval of the drug for marketing. Until that approval is obtained, the drug may not be commercialized. Although the statute requires FDA to act upon an NDA within 6 months, approval actually takes longer to obtain. The House Subcommittee Report found that the average NDA approval time was 14 months in 1963 and climbed to 35.2 months in 1979. During this substantial amount of time, the new drug cannot be marketed.

Summary. The House Subcommittee Report documents a period of 7-13 years to satisfy the requirements for preclinical research, clinical investigation, and NDA approval for a pioneer prescription new drug. This is in addition to the time needed to synthesize the new chemical entity before the drug development process itself can begin.

In contrast with this lengthy process that is required of the pioneer manufacturer, the generic manufacturer may spend only about 2 years to copy the pioneer drug, do the required testing, and obtain the expedited FDA approval that exists for these generic products.[15] Thus, generic manufacturers have an enormous competitive advantage in copying the results of the research of pioneer manufacturers, with little investment and no risk.

---

[13] Note 11 *supra.*

[14] 21 C.F.R. Parts 50, 56, 312, 314.

B. The Cost of Developing a Pioneer Prescription New Drug Has Escalated.

The cost of developing and obtaining approval of a pioneer prescription new drug has risen dramatically since 1962. It is estimated that about 10,000 candidate drugs are synthesized for every one that actually gets to market. For every ten drugs that reach the very expensive and time-consuming clinical investigation (IND) stage, only one is ultimately marketed.[16] The costs of chemical, animal, and clinical testing of pioneer new drugs have soared. As a result, the total amount of investment needed to produce a single approved pioneer new drug has increased exponentially.

The economic literature discloses several studies of the increase in the cost of developing a pioneer new drug in real dollars during the past 20 years. As demonstrated below, these studies show that the average cost of an approved pioneer new drug for 1962 was $6.5 million, and after 1962 it was $44.7 million, in 1980 dollars.[17]

---

[15] Petition for writ of certiorari, p. 4.

Unlike pioneer drug manufacturers, generic manufacturers do not conduct original research to discover new active drug ingredients. Rather, they take active drug ingredients developed by pioneer manufacturers and formulate products that are copies of the pioneer new drug product, except that the generic products may have different binders and excipients. Generic manufacturers do not perform the lengthy and expensive preclinical research and clinical investigations to show drug safety and effectiveness that are required of pioneer manufacturers. Instead, to obtain FDA approval of their products, generic manufacturers need only conduct short-term and thus inexpensive tests to show that their generic copies will perform in the same way as the pioneer drug product, that is, tests to show bioavailability (ability of the active ingredient to get into the bloodstream) and bioequivalence (equivalent rate and extent of absorption of the active ingredient). The results of these tests are submitted to FDA in an "abbreviated new drug application" (ANDA). This ANDA procedure permits expedited FDA approval of generic drug products. *See* 21 C.F.R. § 314.2 and Part 320.

[16] Wardell, "The History of Drug Discovery, Development and Regulation," in R.I. Chien, ed., *Issues in Pharmaceutical Economics* 10, 11 (1979).

Schwartzman found the R&D cost per pioneer new drug to be $1.3 million in 1960 and $24.3 million in 1973, excluding the cost of capital.[18] Adjusting these figures to 1980 dollars ($3.7 million and $48.6 million), this reflects a 13-fold increase in the real cost of a pioneer new drug in this 10-year period.

Sarett found the cost per approved drug (not per pioneer new drug) in one pharmaceutical firm to be $1.2 million in 1962, $3.0 million in 1967, and $11.5 million in 1972, excluding the cost of unsuccessful projects, capital, and discovery research.[19] Adjusting the 1962 and 1972 figures to 1980 dollars ($3.4 million and $25.9 million), they reveal a 7.6-fold increase in this 10-year period.

Mansfield[20] and Schnee[21] jointly studied some 75 drug research projects undertaken in one pharmaceutical firm during the period 1950 to 1957. For the period prior to 1962, R&D cost per marketed pioneer new drug was $1.1 million, or $3.1 million in 1980 dollars, excluding the cost of capital and discovery research.

Clymer found that the R&D cost for a marketed pioneer new drug in one pharmaceutical company in 1971 was $12 million.[22]

---

[17] *See* Appendix A, summarizing the results of the studies.

[18] Schwartzman, *Innovation in the Pharmaceutical Industry* 65-70 (1976).

[19] Sarett, "Impact of Regulations on Industrial R&D: FDA Regulations and Their Influence on the Future of R&D," *Research Management* 18 (March 1974).

[20] Mansfield, Panel Discussion, in J.D. Cooper, ed., *Economics of Drug Innovation* 149 (1969).

[21] Schnee, "Development Costs, Determinants and Overruns," *Journal of Business* 347 (July 1972).

[22] Clymer, "The Economics of Drug Innovation," in Parnowski & Darrach, ed., *The Development and Control of New Drug Products* 109 (1972).

Clymer also found that the R&D discovery cost amounts "to at least as much as the development costs" for a pioneer new drug, thus making the total costs approximately $24 million in 1971 or $56.5 million in 1980 dollars, excluding the cost of capital.[23]

Hansen, using an accounting approach, directly studied R&D expenditures based on a sample of new chemical entity drugs from several drug companies.[24] He found the average cost between 1963 and 1975 to be $54 million. Expressed in 1980 dollars, this amounts to $70 million including the cost of capital and $47.6 million excluding the cost of capital.

Baily developed a model of new product development and applied it to the pharmaceutical industry on the basis of aggregate industry figures.[25] He projected $6 million per pioneer new drug before 1962, or $16 million in 1980 dollars.

The table in Appendix A summarizes these 6 studies. These figures do not, of course, show the increase in real R&D cost per approved pioneer drug for the past 10 years. They show only the increase during the 10-year period from about 1962 to 1972. If figures were available during the past 10 years, they would show a further increase in the real R&D cost per approved pioneer new drug. Nonetheless, the available studies show that the average cost of an approved pioneer new drug before 1962 was $6.5 million, and after 1962 it was $44.7 million, in 1980 dollars. This represents a real 6.9-fold increase even without including the cost of capital.

Thus, for any given level of research and development investment by the pharmaceutical industry today, the country realizes fewer pioneer new drugs than it once did. Because of this decrease in real investment by the industry, it is not surprising that a 1983 study by the National Academy of Engineering documented a substantial decline in pharmaceutical innovation in the United States:[26]

---

[23] Clymer, "The Changing Costs and Risks of Pharmaceutical Innovation," in J.D. Cooper, ed., *Economics of Drug Innovation* 123 (1969).

[24] Hansen, "The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effects of Proposed Regulatory Changes," in R.I. Chien, *Issues in Pharmaceutical Economics* 151 (1979).

[25] Baily, *Research and Development Costs and Returns: The U.S. Pharmaceutical Industry*, 80 J. Pol. Economy 78 (January/ February 1972).

> "Data compiled by this study indicate a clear relative deterioration in the foundation of pharmaceutical competitive position — the research efforts necessary for discovery and introduction of new patented drugs."

Strong patent protection is an essential element in reversing this deterioration.

C. The Effective Patent Life of a Pioneer Prescription New Drug Has Been Cut in Half as a Result of FDA Regulatory Requirements.

Although Congress has not changed the 17-year patent term for pharmaceutical products, the increase in FDA research, testing, and approval requirements just described has reduced the effective patent life of a pioneer prescription new drug by half.

When a research-intensive pharmaceutical firm discovers a new chemical compound with promising biological activity, the first thing it does is to file for a patent, even before making the investment to develop the entity into a marketable medicine. Once that patent is issued, its 17-year term immediately begins to run. But at the time the patent is issued, the innovating firm may be far from sure it will ever develop a marketable drug. For that assurance, the law requires FDA approval of an NDA which, as documented above, takes 7-13 years to obtain.

For pharmaceutical products, therefore, the 17-year patent term has become a legislative figment. In reality, a drug patent has a much shorter effective life. As a result, incentives to invest in pharmaceutical research and development have been substantially reduced.

---

[26] National Academy of Engineering, *The Competitive Status of the U.S. Pharmaceutical Industry* 1 (1983).

The erosion of effective patent life[27] for pharmaceutical products began about 20 years ago. It coincides with the erosion in pharmaceutical innovation, as measured by the yearly FDA approval of pioneer new drugs.

A number of studies have been conducted regarding the precise reduction that has occurred in the effective patent life for pioneer prescription new drugs during the past twenty years. All studies show the same trend. Both individually and in combination, they confirm a substantial decrease in effective drug patent terms. The effective patent life of the pioneer new drugs approved by FDA in 1980 and 1981 was less than half the 17 years provided by Congress under the patent law.

Pracon, Inc., an independent consulting firm, found that the average effective patent life of pioneer new drugs approved by FDA during the period 1950 to 1977 was reduced from 12.9 years to 8.8 years between 1966 and 1977.[28]

Schwartzman studied the pioneer new drugs approved by FDA during 1966 to 1973.[29] He calculated the arithmetic mean of their effective patent life during this time to be 13.1 years. Moreover, he found a progressive reduction in the average effective patent life during that period, from 13.9 years between 1966 and 1973 to 12.4 years between 1970 and 1973.

Statman studied a sample of 126 pioneer new drugs approved by FDA between 1949 and 1975.[30] He found "a continuous decline in the effective life of drug patents" and developed an equation to estimate the effective life of drug patents for 1960 to 1978.

---

[27] Note 10 *supra.*

[28] Pracon, Inc., *The Effective Patent Life of Pharmaceutical Products: Trends and Implications* (1978).

[29] Schwartzman, *Innovation in the Pharmaceutical Industry* 167-173 (1976).

[30] Statman, "The Effect of Patent Expiration on the Market Position of Drugs," in R.B. Helms, ed., *Drugs and Health: Economic Issues and Policy Objectives* 140 (1980) and in *Managerial and Decision Economics* 61 (June 1981).

Eisman and Wardell studied the effective life of pioneer new drug patents during 1966 to 1979.[31] They found the average effective patent life declined from 13.6 years in 1966 to 9.5 years in 1979.

The Pharmaceutical Manufacturers Association obtained additional data for the year 1980.[32] They show that, for pioneer new drugs approved by FDA in 1980, the average effective patent life decreased still further, to 7.4 years.

Wardell recently obtained the patent data for pioneer new drugs approved by FDA in 1981. They show an even lower average effective patent life of 6.8 years.[33]

In order graphically to illustrate the results of these studies, they are plotted on the chart shown in Appendix B. The congruence of these studies is striking.

II. The Unlicensed Use Of Patented Drugs For The Purpose Of Developing Generic Drug Products And Conducting The Tests Required For FDA Approval Directly Injures The Patent Holder.

The patent law specifically defines as an illegal infringer any person who "makes, uses, or sells" a patented product during the term of the patent. 35 U.S.C. § 271(a). There are sound reasons why the law thus prohibits *any* "use" of a patented product while the patent remains valid and unexpired, as illustrated by the situation involved in this case.

Use of a patented drug, in violation of a valid unexpired patent, directly injures the patent holder by depriving the patent holder of profits from the sale or licensing of the drug to other drug manufacturers, during the patent term, for whatever testing is necessary to satisfy regulatory requirements.

---

[31] Eisman & Wardell, "The Decline in Effective Patent Life of New Drugs," *Research Management* 18 (January 1981).

[32] "Patent Term Extension and Pharmaceutical Innovation," Hearing before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, House of Representatives, 97th Cong., 2d Sess. 159-160 (1982).

[33] *Id.* at 110-112.

Research-intensive pharmaceutical companies may sell an active ingredient to another drug manufacturer, or may license another drug manufacturer to make or use an active ingredient, during the term of a patent. Such contractual arrangements permit the other manufacturers to conduct the testing necessary to satisfy FDA regulatory requirements before the patent expires. Such sales or licenses generate profits for the patent holder.

Bolar seeks to obtain the benefits of such an arrangement without any license from Roche. In effect, Bolar is appropriating unto itself a compulsory license without compensation. The patent law nowhere provides for such an extraordinary result. Congress has on several occasions explicitly declined to enact legislation that would require compulsory patent licensing, either for all patents generally or for new drug patents in particular, even with compensation.[34] For this reason alone, Bolar's arguments were properly rejected by the Court of Appeals.

---

[34] *E.g.*, S. 1552, 87th Cong., 1st Sess. (1961) (Kefauver); H.R. 6245, 87th Cong., 1st Sess. (1961) (Celler); S. 1297, 88th Cong., 1st Sess. (1963) (Kefauver); S. 2287, 93d Cong., 1st Sess. (1973) (Hart); H.R. 915, 97th Cong., 1st Sess. (1981) (Rosenthal). *See* "Drug Industry Antitrust Act," Hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, United States Senate, 87th Cong., 1st Sess., Parts 1-5 (1961); "Administered Prices — Drugs," S. Rep. No. 448, 87th Cong., 1st Sess. (1961); "Drug Industry Antitrust Act," Hearings before the Antitrust Subcommittee of the Committee on the Judiciary, House of Representatives, 87th Cong., 2d Sess. (1962). Congress has adopted compulsory licensing only for particular areas such as air pollution technology, 42 U.S.C. § 7404, and atomic energy, 42 U.S.C. § 2183.

III. The Federal Circuit Properly Declined To Create For Generic Drug Companies A New Exception To The Use Prohibition Which Would Further Erode Patent Protection For Pioneer New Drugs And Would Thus Be Contrary To The Patent Law And Harm Public Health In The United States.

The patent law clearly provides that the unlicensed use of a patented product during the patent term is an infringement. Bolar asked the Court of Appeals to create an exception to this use prohibition that would allow generic drug companies to use patented pioneer new drugs, without license from the patent holder, to conduct all of the necessary formulation and tests to obtain FDA approval of the generic drug product before expiration of the patent term. This would allow generic drug companies to offer their products in competition with the patented product immediately upon expiration of the patent, rather than requiring them to comply with the requirements of the Federal Food, Drug, and Cosmetic Act after expiration of the patent. In essence, Bolar requested permission from the Federal Circuit to violate the patent law in order to avoid marketing delays imposed by the federal drug law and FDA regulatory requirements. The Court of Appeals properly refused to create this exception for generic drug companies.

This Court has repeatedly recognized and reinforced "the policy of stimulating invention that underlies the entire patent system."[35] Without the stimulus of the temporary period of exclusivity provided under the patent law, there would be far less incentive for pharmaceutical companies to invest their funds in risky pharmaceutical R&D ventures than in other competing investment opportunities.[36]

The data discussed above document the substantial decline since 1962 in the effective patent life of pharmaceutical products, the increase in the cost of developing pioneer new drugs, and the reduction in pharmaceutical innovation. The importance of patent protection obviously increases with the size of the investment needed to achieve innovation in any field. If innovation can be purchased cheaply patent protection is relatively unimportant. As the investment cost escalates, however, patent protection becomes far more important. In the pharmaceutical industry, where the cost of a pioneer new drug has escalated so dramatically, the assurance of strong patent protection has become increasingly crucial to the future of the industry. This fact has been explicitly recognized in recent reports by the National Academy of Engineering[37] and by the Office of Technology Assessment,[38] in the Patent Amendments of 1980,[39] and in a 1968 General Accounting Office report on pharmaceutical research.[40] Without an adequate patent system, innovation in the pharmaceutical industry would wither and the public health would correspondingly suffer.

---

[35] Dawson Chemical Co. v. Rohm & Haas Co., 448 U.S. 176, 221 (1979).

[36] This was recognized by the court in Eli Lilly and Co. v. Premo Pharmaceutical Laboratories, Inc., 630 F.2d 120, 137 (3d Cir.), *cert. denied*, 449 U.S. 1014 (1980).

Pioneer new drugs represent our major hope as a society for reducing the burden of morbidity and mortality in this country. The infectious diseases that took such a heavy human toll at the turn of the century now cause less than 2 percent of the deaths they caused then.[41] Diseases dreaded as recently as 30 years ago now largely are under control. New pharmaceutical products have played a key role in the declining rates of death and disease for a wide variety of serious disease categories.[42] New medicines to achieve the same dramatic results against our current leading causes of death — heart disease and cancer — are now major targets for the pharmaceutical industry. Pharmaceutical innovation is also a primary means through which the skyrocketing costs of health care can be brought under control and perhaps eventually even reduced.

---

[37] National Academy of Engineering, *The Competitive Status of the U.S. Pharmaceutical Industry* 79-80 (1983).

[38] Office of Technology Assessment, *Patent Term Extension and the Pharmaceutical Industry* 28 (1981).

[39] 94 Stat. 3015, 3019 (1980).

[40] General Accounting Office, *Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry*, Report No. B-164031(2), 18-19 (1968).

[41] Fries, "Aging, Natural Death, and the Comprehension of Morbidity," 303 *New Eng. J. Med.* 130, 132 (July 17, 1980).

[42] These disease categories include measles, mumps, rheumatic fever, rubella, tuberculosis, whooping cough, and meningitis. *See* National Center for Health Statistics, *Monthly Vital Statistics Reports — Annual Summary*

Extraordinary investments are needed to assure that the insights provided by new scientific information are translated into pioneer new drugs in the future. Whether those investments will occur, however, depends in substantial part upon the incentives provided by a strong patent system. By preserving the integrity of the patent term of pioneer new drugs against attempted encroachment by generic drug companies, the Court of Appeals has preserved the current and necessary stimulus to innovation in the pharmaceutical industry.

---

of Births, Deaths, Marriage and Divorce: United States, 1980, Vol. 29, No. 13, p. 20 (1981); National Center for Health Statistics, *Vital Statistics of the United States, 1960*, Vol. 2, Pt. A, pp. 5-102 (1961); U.S. Department of Health and Human Services, *Morbidity and Mortality Weekly Report — Annual Summary, 1981*, Vol. 29, No. 56, pp. 12 & 14 (September 1981); U.S. Department of Health, Education and Welfare, *Morbidity and Mortality Weekly Report — Annual Supplement, 1961*, Vol. 29, No. 54, p. 4 (September 1961).

CONCLUSION

For the reasons set forth above, the petition for a writ of certiorari should be denied.

Respectfully submitted,

PETER BARTON HUTT
(Counsel of Record)
ELLEN J. FLANNERY
COVINGTON & BURLING
1201 Pennsylvania Avenue. N.W.
P.O. Box 7566
Washington, D.C. 20044
(202) 662-5522
Attorneys for Amicus Curiae
Pharmaceutical Manufacturers
Association

Of Counsel:
BRUCE J. BRENNAN
Vice President and General Counsel
Pharmaceutical Manufacturers Association
1100 Fifteenth Street, N.W.
Washington, D.C. 20005

August 31, 1984

APPENDICES

APPENDIX A

Real Research and Development Costs per Pioneer Prescription New Drug: 1962-1972

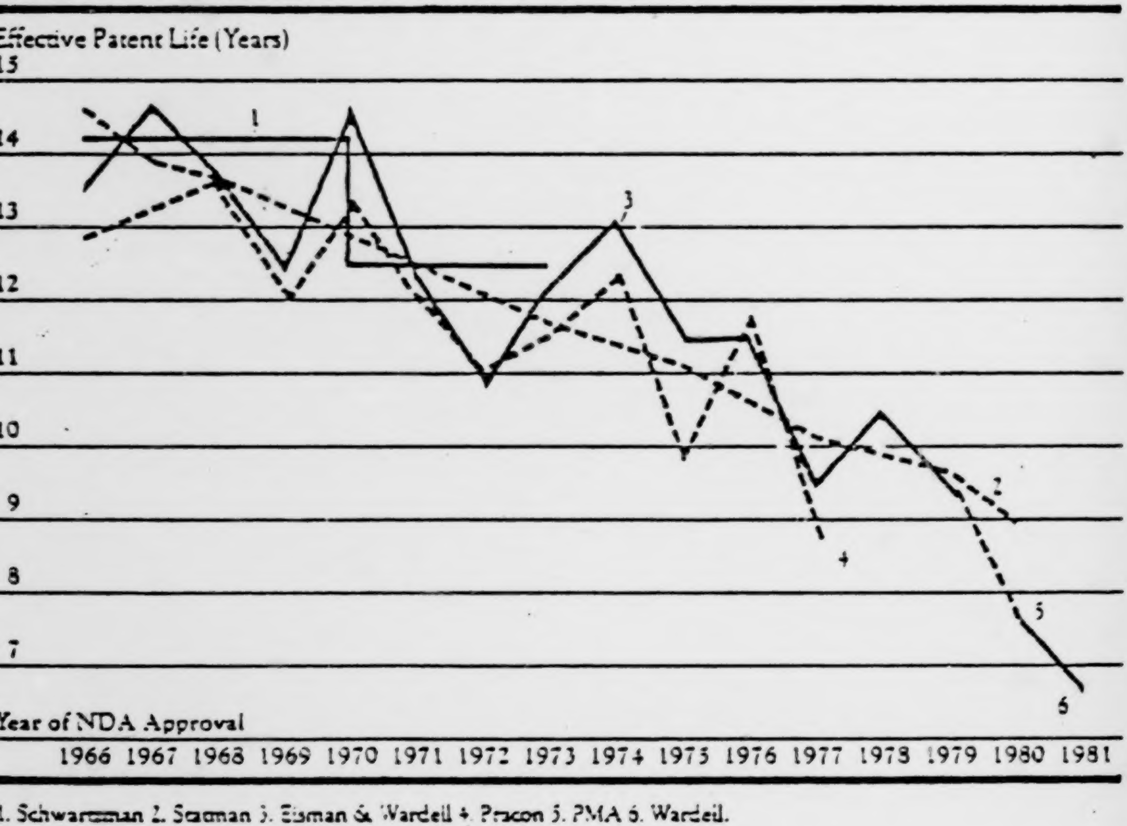
	Pre-1962	Post-1962
Schwartzman	3.7	48.6
Sarett	3.4	25.9
Mansfield/Schnee	3.1	—
Clymer	—	56.5
Hansen	—	47.6
Baily	16.0	—
Average	6.5	44.7

NOTE: All figures adjusted to 1980 dollars.

APPENDIX B

Trends In Average Effective Patent Life Of Pioneer Prescription New Drugs, 1966-1981

Trends In Effective Patent Life From Various Sources



Office - Supreme Court, U.S.
FILED
AUG 31 1984
ALEXANDER L. STEVAS.
CLERK

(3)

No. 84-130

In The

Supreme Court of the United States

October Term, 1984

Bolar Pharmaceutical Co., Inc.,
Petitioner,
v.
Roche Products Inc.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF RESPONDENT IN OPPOSITION

John C. Vassil
345 Park Avenue
New York, New York 10154
(212) 758-4800
Counsel of Record for Respondent

Of Counsel:

Stephen R. Smith
J. Robert Dailey
Janet Dore
Morgan, Finnegan, Pine, Foley & Lee

Jack Lipson
Michael T. Shor
Arnold & Porter
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036

Ralph N. Del Deo
Crummy, Del Deo, Dolan & Purcell
A Professional Corporation
Gateway 1
Neward, New Jersey 07102
07102

August 31, 1984

BEST AVAILABLE COPY

22 pp

COUNTERSTATEMENT OF QUESTIONS PRESENTED

1. Should this Court review the holding of the Court of Appeals for the Federal Circuit that the unauthorized use of a patented compound during the term of the patent solely for the user's business purposes constitutes infringement of that patent under 35 U.S.C. § 271(a)?

2. Should this Court grant certiorari to determine whether the Court of Appeals for the Federal Circuit erred in refusing to create a new exception to the patentee's right to exclude others from use of his patented invention during the seventeen-year term of his valid patent, as codified in the plain language of the patent statute (35 U.S.C. § 271(a)) and recognized for nearly 200 years of patent law, when the use by the infringer admittedly was to prepare to market commercially the patented invention and the infringer expressly conceded that the use was not within the scope of the experimental use exception?

PARTIES TO THE PROCEEDINGS BELOW

The parties named in the caption are the only parties to this action. Respondent's statement pursuant to Rule 28.1 is set forth in the margin.*

---

* Roche Products Inc. is a Panamanian corporation licensed to do and doing business in Puerto Rico. It is wholly owned by Caribbean Trade and Holding Company Limited SA (a Panamanian corporation) which in turn is a wholly owned subsidiary of Sapac Corporation, Ltd. of New Brunswick, Canada ("Sapac"). The voting shares of Sapac are held in trust for the benefit of F. Hoffmann-LaRoche & Co. Limited Company, Basle, Switzerland, a Swiss corporation ("Roche Basle"). Sapac's non-voting shares are linked to the shares of Roche Basle. The linked shares are publicly owned, quoted and traded in Switzerland. Roche Products Inc. has no affiliation with any companies apart from members of the Roche Basle and Sapac group of companies.

TABLE OF CONTENTS

Page

COUNTERSTATEMENT OF QUESTIONS PRESENTED i

PARTIES TO THE PROCEEDINGS BELOW ii

TABLE OF AUTHORITIES iv

OPINIONS BELOW 1

COUNTERSTATEMENT OF THE CASE 2

REASONS FOR DENYING THE WRIT 4

- I NO JUSTIFICATION WARRANTING REVIEW OF THE COURT OF APPEALS WITH NATIONWIDE JURISDICTION OVER PATENT APPEALS IS PRESENT IN THIS CASE 5
- II IN DECIDING THAT BOLAR'S ACTIVITIES FELL OUTSIDE THE SCOPE OF PERMISSIBLE "EXPERIMENTAL USE," THE CAFC APPLIED WELL-ESTABLISHED PRINCIPLES 6
  - A. It Is Hornbook Patent Law that the Use of a Patented Compound for Purposes of Commercially Exploiting that Compound Cannot Be Considered a Non-Infringing "Experimental Use" 6
  - B. This Court Should Decline To Expand the "Experimental Use" Exception 9
- III THE PATENT CASES RELIED UPON BY BOLAR DO NOT SANCTION ITS INFRINGING USE OF ROCHE PRODUCTS' PATENT DURING THE PATENT TERM 11
- IV THERE IS NO CONFLICT BETWEEN THE CAFC'S DECISION AND DECISIONS OF THIS COURT PROHIBITING THE EXTENSION OF PATENT "MONOPOLIES" 13

CONCLUSION 15

TABLE OF AUTHORITIES

Page

CASES

Adams v. *Burke,* 84 U.S. 453 (1873) 12

Akro Agate Co. v. *Master Marble Co.,* 18 F. Supp. 305 (N.D. W. Va. 1937) 13

Albright v. *Celluloid Harness-Trimming Co.,* 1 F. Cas. 320 (C.C.D.N.J. 1887) (No. 147) 12

Becton Dickinson & Co. v. *R.P. Scherer Corp.,* 211 F.2d 835 (6th Cir. 1954) 11

Beedle v. *Bennett,* 122 U.S. 71 (1887) 11

Brulotte v. *Thys Co.,* 379 U.S. 29 (1964) 13

Carter Crume Co., Ltd. v. *American Sales Book Co.,* 124 F. 903 (C.C.W.D.N.Y. 1903) 12

Celotex Corp. v. *V.E. Power Door Corp.,* 204 U.S.P.Q. 636 (E.D.N.Y. 1979) 13

Del Mar Engineering Laboratories v. *Physio-Tronics, Inc.,* 202 U.S.P.Q. 242 (C.D. Cal. 1978), *aff'd,* 642 F.2d 1167 (9th Cir. 1981) 11-12

Flat Slabs Patents Co. v. *Wright, Barrett & Stilwell Co.,* 283 F. 345 (D. Minn. 1920) 12

Fulton Co. v. *Bishop & Babcock Co.,* 17 F.2d 1006 (6th Cir. 1927) 14

Kaz Mfg. Co., Inc. v. *Chesebrough-Pond's, Inc.,* 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd,* 317 F.2d 679 (2d Cir. 1963) 12

Keeler v. *Standard Folding Bed Co.,* 157 U.S. 659 (1895) 12

Kellogg Co. v. *National Biscuit Co.,* 305 U.S. 111 (1938) 14

Levin v. *Ripple Twist Mills, Inc.,* 416 F. Supp. 876 (E.D. Pa. 1976), *appeal dismissed,* 549 F.2d 795 (3d Cir. 1977) 13

Maxon Premix Burner Co. v. *Eclipse Fuel Engineering Co.,* 471 F.2d 308 (7th Cir. 1972), *cert. denied,* 410 U.S. 929 (1973) 13

Mercoid Corp. v. *Mid-Continent Investment Co.,* 320 U.S. 661 (1944) 11

Page

Motion Picture Patents Co. v. *Centaur Film Co.,* 217 F. 247 (D.N.J. 1914) 14

Neff Instrument Corp. v. *Cohu Electronics, Inc.,* 269 F.2d 668 (9th Cir. 1959) 11

Pfizer, Inc. v. *International Rectifier Corp.,* 217 U.S.P.Q. 157 (C.D. Cal. 1982) 8

Pitcairn v. *United States,* 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied,* 434 U.S. 1051 (1978) 8

Poppenhusen v. *Falke,* 19 F. Cas. 1048 (C.C.S.D.N.Y. 1861) (No. 11, 279) 7

Radio Corp. of America v. *Andrea,* 15 F. Supp. 685 (E.D.N.Y. 1936), *modified on other grounds,* 90 F.2d 612 (2d Cir. 1937) 8,14

Roche Products, Inc. v. *Bolar Pharmaceutical Co., Inc.,* 733 F.2d 858 (Fed. Cir. 1984) .... *passim*

Scott Paper Co. v. *Marcalus Mfg. Co.,* 326 U.S. 249 (1945) 14

Singer Mfg. Co. v. *June Mfg. Co.,* 163 U.S. 169 (1896) 14

Technicon Instruments Corp. v. *Coleman Instruments, Inc.,* 255 F. Supp 630 (N.D. Ill. 1966), *aff'd,* 385 F.2d 391 (7th Cir. 1967) 12

Underwood Typewriter Co. v. *Elliott-Fisher Co.,* 156 F. 588 (C.C.S.D.N.Y. 1907) 14

United States v. *General Electric Co.,* 272 U.S. 476 (1926) 12

United States v. *Generix Drug Corp.,* 460 U.S. 453, 103 S. Ct. 1298 (1983) 4

Upjohn Mfg. Co. v. *Schweiker,* 681 F.2d 480 (6th Cir. 1982) 14

Whittemore v. *Cutter,* 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No.17,600) 7

STATUTES

28 U.S.C. § 1295 5

28 U.S.C. § 1338 5

35 U.S.C. § 154 2,6

35 U.S.C. § 261 12

	Page
35 U.S.C. § 271(a)	2,6,12
35 U.S.C. § 281	5
Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982)	5

CONGRESSIONAL MATERIAL

H.R. 3605, Patent Restoration and Related Bills: Hearing Before the Subcomm. on Civil Liberties and the Admin. of Justice of the House Comm. on the Judiciary, 89th Cong., 2d Sess. 22 (June 27, 1984)	8
H.R. Rep. No. 312, 97th Cong., 1st Sess. (1981)	5
S. Rep. No. 275, 97th Cong., 1st Sess. (1981)	5
S. 2926, 98th Cong., 2d Sess. § 202, 130 Cong. Rec. § 10512 (daily ed. Aug. 10, 1984)	10
127 Cong. Rec. H8390 (daily ed. Nov. 17, 1982)	6

MISCELLANEOUS

Bee, *Experimental Use as an Act of Patent Infringement,* 39 J. Pat. Off. Soc'y 357 (1957)	7
C. Haworth & C. Meader, *A Proposed New Federal Intermediate Appellate Court,* 12 Univ. Mich. J. Law Reform 201 (1979)	5
3 W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890)	8-9
48 C.J., *Patents* § 496 (1929)	9
69 C.J.S., *Patents* § 288 (1951)	9

In The

Supreme Court of the United States

October Term, 1984

No. 84-130

Bolar Pharmaceutical Co., Inc.,
Petitioner,
v.
Roche Products Inc.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

---

BRIEF OF RESPONDENT IN OPPOSITION

Respondent, Roche Products Inc. ("Roche Products"), respectfully requests that the Court deny Bolar Pharmaceutical Co., Inc.'s ("Bolar") Petition for a Writ of Certiorari. Neither the questions presented nor the reasons given by petitioner for grant of the writ provide appropriate bases for the exercise of this Court's discretionary jurisdiction.

OPINIONS BELOW

The decision of the District Court for the District of New Jersey granting Roche Products a temporary restraining order is unpublished but is reproduced at 21a-27a.[1] The opinion of the District Court for the Eastern District of New York holding non-infringement and denying Roche Products an injunction is reported at 572 F. Supp. 255 (1983) (31-37a). The opinion of the Court of Appeals for the Federal Circuit ("CAFC") reversing the District Court is reported at 733 F.2d 858 (1984) (1a-18a), and its judgment is reproduced at 39a. The mandate of the CAFC issued on May 15, 1984.

---

[1] Appendix references will be to the numbered pages of the Appendices to Bolar's Petition.

COUNTERSTATEMENT OF THE CASE

This action involves the use by Bolar of Roche Products' patented invention, flurazepam hydrochloride, in the closing months of the patent's term for Bolar's own business purposes.[2] Roche Products' patent is admitted to be for a pioneer invention and to be valid and enforceable (32a). Bolar has also admitted it possessed the patented compound and intended to use it prior to the expiration of the patent in conducting the tests required to obtain Food and Drug Administration ("FDA") approval to market commercially its generic version of Roche Products' DALMANE brand prescription product (33a). The actual extent of Bolar's use will be determined by the district court below on remand. The parties have acknowledged that Roche Products had not authorized Bolar to make, use or sell flurazepam (33a).

Roche Products filed suit for declaratory judgment and injunctive relief to enforce its right to exclude Bolar from "making, using or selling" the patented invention during the life of the patent (35 U.S.C. §§ 154, 271(a)). The CAFC found that Bolar's intended use of flurazepam was solely for business reasons and held that such use constituted infringement of Roche Products' patent (9a).

Bolar terms Roche Products' successful enforcement of its vested legal rights "patent extension." Such terminology is misleading because it implies, incorrectly, that the decision below alters the term of Roche Products' patent. That term was fixed, by statute, at seventeen years as of the date the patent was granted on January 17, 1967, and has not been extended even one day by the decision below. Immediately upon the expiration of the patent, on January 17, 1984, Bolar and all others were free to make, use and sell flurazepam.

---

[2] Roche Products owns patent 3,299,053 by mesne assignments from the original owner, Hoffmann-LaRoche Inc. of Nutley, N.J., which in turn obtained rights to the patent and the invention from its employee inventors. The patented compound, flurazepam hydrochloride, will be referred to hereinafter as "flurazepam" for convenience. Capsules for oral administration containing 15 mg. or 30 mg. of flurazepam as the active ingredient are the standard dosage forms of the DALMANE brand prescription product marketed by Roche Products.

Bolar's inability to market flurazepam as a dosage form prescription product (*i.e.*, as its generic version of DALMANE) immediately upon the expiration of Roche Products' patent is simply a collateral consequence of the FDA regulatory process. This regulatory process had delayed Roche Products' predecessor's ability to market dosage form flurazepam products just as severely as it now delays Bolar. Roche Products' predecessor also had to obtain FDA approval prior to marketing flurazepam products. Documents publicly available from the FDA and the Patent Office reveal that Roche Products' predecessor submitted its Investigational New Drug Application to the FDA in August 1963, applied for its patent in February 1964, obtained the patent in January 1967, submitted its New Drug Application to the FDA in November 1967, and obtained approval from the FDA in April 1970. Thus, by the time Roche Products' predecessor received FDA approval to market DALMANE, it had already lost more than three years of the seventeen year life of the patent.

Significantly, Bolar's intended and actual use of flurazepam during the patent term had but one purpose—the commercial exploitation of that compound. Its FDA-related testing activities would not and could not be characterized as research and development, because Bolar never intended or expected to discover a new substance or anything innovative. In order to obtain regulatory approval, Bolar would first have to determine what fillers, binders and excipients it should use with flurazepam in formulating its generic dosage form. Second, it would have to perform stability, dissolution and bioequivalency tests to demonstrate to the FDA that its product is comparable to Roche Products' DALMANE. Neither of these steps is innovative.

The process of producing a generic equivalent to a patented drug is not one of innovation and creativity; it is one of copying. As this Court has noted:

> "Generic drugs, also called 'copycat' or 'me-too' drugs, are usually marketed at relatively low prices because their manufacturers do not incur the research, development, and promotional costs normally associated with the creation and marketing of an original product." *United States* v. *Generix Drug Corp.*, 460 U.S. 453, 103 S. Ct. 1298, 1299 n.1 (1983).

Such commercially based use does not fall within the recognized limits of permissible experimental use as Bolar now suggests. Bolar conceded as much before both the district court and the CAFC, and the CAFC properly declined to create a new exception to permit such an encroachment on Roche Products' statutory property rights.

Bolar asserts that it was common practice and custom for drug companies to use a patented product for FDA testing and approval "well in advance" of patent expiration without objection from the patentee. (Pet. at 4.) While an affidavit alleging such a practice was filed by Bolar in the district court, the claim was disputed by Roche Products. Bolar offered no independent evidence to support its claim, and the district court did not find that any such practice existed. Bolar abandoned the contention on appeal. The practice and custom to which Bolar refers does not exist.

REASONS FOR DENYING THE WRIT

This case does not meet the accepted standards for discretionary review. There is no conflict between the CAFC's decision and a prior decision of another court of appeals, and none is alleged. No conflict exists between the CAFC's decision and a decision of the highest court of any state, and no conflict exists between the CAFC's decision and any decision of this Court, notwithstanding Bolar's assertion to the contrary. Finally, the CAFC's decision does not decide any new and important issues of federal law which should be settled by this Court. Rather, the CAFC decision applies well-settled principles of patent law.[3]

I

NO JUSTIFICATION WARRANTING REVIEW OF THE COURT OF APPEALS WITH NATIONWIDE JURISDICTION OVER PATENT APPEALS IS PRESENT IN THIS CASE

In 1982, Congress conferred upon the newly established CAFC exclusive appellate jurisdiction over patent-related cases.[4] 28 U.S.C. §§ 1295(a)(1) and (4). The intent of Congress was to "reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist in the administration of patent law." H.R. Rep. No. 312, 97th Cong., lst Sess. 23 (1981) (hereinafter "House Report").[5]

Congress intended that the CAFC's patent decisions would have special authoritativeness, expressly recognizing that "[d]ecisions of this court will have precedential effect throughout the country; . . ." S. Rep. No. 275, 97th Cong., 1st Sess. 7 (1981). Congress contemplated that the need for Supreme Court review of patent law decisions would thereby be lessened. As the bill's sponsor in the House (and chairman of the subcommittee responsible for reporting the bill) stated before the full House in introducing the bill, the CAFC "will relieve docket pressure both on the regional appellate courts *and on the Supreme Court.*" 127 Cong. Rec. H8390 (daily ed. Nov. 17, 1981) (statement of Rep. Kastenmeier) (emphasis added).

---

[3] The additional attempt by Bolar to inject a factual issue of alleged practice and custom, after abandoning that same issue below, is plainly inappropriate in a petition for certiorari (32a).

[4] The CAFC was established, and its jurisdiction defined, by the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982) (hereinafter "Courts Act").

[5] The Court of Customs and Patent Appeals, which was replaced by the CAFC, did not have exclusive jurisdiction over patent-related appeals. Several appellate fora were available, depending upon the nature of the action. For example, jurisdiction of suits for infringement of patents or for declaratory judgments of noninfringement was and remains vested in the federal district courts. 28 U.S.C. § 1338; 35 U.S.C. § 281. The Courts Act, however, transferred appellate jurisdiction from the twelve circuit courts of appeals to the CAFC. *See* 28 U.S.C. § 1295(a)(2). *See generally* C. Haworth & C. Meader, *A Proposed New Federal Intermediate Appellate Court,* 12 Univ. Mich. J. Law Reform 201, 215-17 (1979); House Report at 22.

In light of the congressional purpose in establishing the CAFC, there is no reason for this Court to review purely patent law issues where no conflict exists with other federal courts and where the CAFC merely has applied well-established law defining the scope of permissible "experimental use."

II

IN DECIDING THAT BOLAR'S ACTIVITIES FELL OUTSIDE THE SCOPE OF PERMISSIBLE "EXPERIMENTAL USE," THE CAFC APPLIED WELL-ESTABLISHED PRINCIPLES

A. It Is Hornbook Patent Law that the Use of a Patented Compound for Purposes of Commercially Exploiting that Compound Cannot Be Considered a Non-Infringing "Experimental Use"

Bolar concedes that Roche Products' patent was valid (32a). It is also uncontested on this record that Bolar, without waiting for that patent to expire, intended to use the patented compound in order to obtain approval from the FDA for post-expiration marketing. As the CAFC stated:

> "In mid-1983, Bolar obtained from a foreign manufacturer 5 kilograms of flurazepam hcl to form into 'dosage form capsules, to obtain stability data, dissolution rates, bioequivalency studies, and blood serum studies' necessary for a New Drug Application to the United States Food and Drug Administration (FDA)." (2a)

Bolar's activities plainly fell within the proscriptions of 35 U.S.C. §§ 154 and 271(a), which grant to a patent holder the right to exclude others from making, *using* or selling the patented invention. Despite concessions below, Bolar now asserts that its activities fell within the "experimental use" exception to infringement. Plainly, they do not. That narrow exception, as defined correctly by the CAFC, applies only to experiments performed on the patented compound for the limited purposes of amusement, to satisfy idle curiosity, or for strictly philosophical inquiry—what we would today call scientific inquiry (6a). *See Whittemore* v. *Cutter,* 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600); *Poppenhusen* v. *Falke,* 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279). *See also* Bee, *Experimental Use as an Act of Patent Infringement,* 39 J. Pat. Off. Soc'y 357 (1957).

The CAFC found that Bolar's unlicensed experiments were conducted with a view to the use of the patented invention in Bolar's business and held this to be a violation of the right of Roche Products to exclude others from using the invention (9a). The CAFC recognized that "no case had permitted a pattern of systematic exploitation of a patented invention for the purpose of furthering the legitimate business interests of the infringer" (9a). Bolar's tests and experiments constitute such systematic exploitation and, as found by the CAFC, were "solely for business reasons" (9a).

The experimental use exception, which Bolar now embraces in this Court (Pet. at 16-20), was expressly disavowed by Bolar before both the district court and the CAFC. In the district court:

> "Bolar concede[d] that its tests do not fall under the infringement exception known as experimentation for philosophical, amusement or curiosity purposes." (33a)

Again on appeal:

> "Bolar concede[d], as it must, that its intended use of flurazepam hcl does not fall within the 'traditional limits' of the experimental use exception as established in these cases or those of other circuits. Its concession here is fatal." (8a)

Indeed, the instant case was not a case of first impression. The decision by the CAFC is consistent with almost 200 years of interpretation of the patent laws upholding the principle that "experimental use" does not, under the guise of experimentation, sanction infringing use that is undertaken "solely for business reasons" (9a) and which is "commercial preparation" (35a) and not "experimental" within the meaning of the patent law.[6]

In *Pfizer, Inc.* v. *International Rectifier Corp.,* 217 U.S.P.Q. 157 (C.D. Cal. 1982), the District Court for the Central District of California held that "[*e*]*very* use" of a patented compound, including use to obtain FDA approval so that the defendant would be "fully equipped and ready to go" into the "domestic and foreign" markets as soon as the patent expired, constituted infringement. *Id.* at 162 (emphasis added). Thus, the two reported cases addressing the specific question petitioner presents to this Court are in complete accord.

Both the decision in *Pfizer* and the decision below recognize as fundamental the principle that the experimental use exception does not apply to one who uses a patented invention for a commercial purpose. Moreover, the Honorable Gerald J. Mossinghoff, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, recently testified that the CAFC's decision below "really amounts to hornbook patent law in my opinion." ***H.R. 3605, Patent Restoration and Related Bills: Hearing Before the Subcomm. on Civil Liberties and the Admin. of Justice of the House Comm. on the Judiciary,*** 98th Cong., 2d Sess. 22 (June 27, 1984) (statement of Gerald J. Mossinghoff) (awaiting publication).

Additionally, a classic authority, which was relied upon by the CAFC and which was cited—but only partially quoted—by Bolar in its petition, states as follows:

> "[W]here it [the patented article] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promo-

---

[6] *See Pitcairn* v. *United States,* 547 F.2d 1106, 1125-26 (Ct. Cl. 1976), *cert. denied,* 434 U.S. 1051 (1978) ("[t]ests, demonstrations, and experiments . . . [which] are in keeping with the legitimate business of the . . . [infringer]" are infringements for which "[e]xperimental use is not a defense"); *Radio Corp. of America* v. *Andrea,* 15 F. Supp. 685 (E.D.N.Y. 1936), *modified on other grounds,* 90 F.2d 612 (2d Cir. 1937) (use of patented invention by testing in preparation for non-infringing extraterritorial sale held infringement).

> tion of the employer's knowledge or the realization afforded to his mind. But if the products of the experiment are sold, or used for the convenience of the experimentor, or if the experiments are conducted with a view to the adaptation of the invention to the experimentor's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent." 3 W. Robinson, *The Law of Patents for Useful Inventions* § 898 at 56 (1890).[7]

Consequently, when the CAFC refused to excuse Bolar's infringing activities, it simply enforced the law as it had been known and applied for years and refused to "create a new exception to the use prohibition" (10a).

B. This Court Should Decline To Expand the "Experimental Use" Exception

The CAFC correctly recognized that true "scientific inquiry" is exempted from patent infringement by the traditional "experimental use" exception. Bolar's argument, that the CAFC decision will prevent meaningful research and development and will stifle scientific creativity, is disingenuous. Neither the court's holding nor its language gives rise to any suggestion that the decision would restrict or delay "scientific inquiry." In its decision, the CAFC stated:

> "unlicensed experiments conducted with a view to adaption of the patented invention to the experimentor's business is a violation of the rights of the patentee. . . . We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes." (9a-10a)

---

[7] *Accord* 48 C.J., *Patents* § 496 (1929); 69 C.J.S., *Patents* § 288 (1951), stating: "Experimental use of a patented invention for the sole purpose of gratifying curiosity or a philosophical taste, or for mere amusement, is not an infringement. . . . This rule, however, cannot be invoked for the protection of one who uses a patented invention commercially, as in the course of business or for profit."

Bolar's suggestion that the experimental use exception should embrace its activities simply because they can be characterized as "tests" blurs the line between true experimental inquiries, *i.e.,* inquiries solely for scientific or philosophical purposes, and commercially oriented testing which is infringing. The CAFC recognized that labeling commercial activities as "scientific inquiry" does not make them such. Bolar admitted, and the district court and the CAFC both found, that Bolar's "tests and experiments" constituted commercial preparation for marketing dosage form products containing the patented compound (35a, 9a). These were not innovative scientific inquiries designed to expand the scope of human knowledge; rather, Bolar was simply using Roche Products' invention and seeking a "copycat" pharmaceutical product.

Bolar also admitted, in its brief before the CAFC, that these experiments and tests would overlap the *normal* manufacturing and formulation requirements it would undertake in preparation for marketing dosage form prescription products containing flurazepam, irrespective of any FDA requirements. Brief for Appellee at 7, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co., Inc.,* 733 F.2d 858 (Fed. Cir. 1984). Bolar's admissions illustrate vividly the Pandora's box of patent infringement litigation which would surely be opened if the definition of experimental use is expanded or a new exception is created.[8] As Judge Sarokin wisely noted in granting the restraining order against Bolar: "[t]o hold otherwise would require a case by case determination of when such preparation could begin and what could be done in expectation of the expiration of the patent" (23a).[9]

---

[8] The use of a patented invention in carrying out various business activities preparatory to commercial exploitation of the invention, which use heretofore has clearly been within the patentee's right to exclude, could arguably be sanctioned in case after case under the guise of obtaining some form of approval, regulatory or otherwise.

[9] Any argument to broaden the experimental use exception to take from patent owners valuable property rights, such as Bolar now urges, is more properly addressed to Congress for such action as may be appropriate within the constraints imposed by the Fifth Amendment's taking clause. Congress is now considering legislation that would affect, to some extent, the scope of experimental use in the future. *See* S. 2926, 98th Cong., 2d Sess. § 202, 130 Cong. Rec. S10512 (daily ed. Aug. 10, 1984).

III

THE PATENT CASES RELIED UPON BY BOLAR DO NOT SANCTION ITS INFRINGING USE OF ROCHE PRODUCTS' PATENT DURING THE PATENT TERM

Bolar's strained interpretation of a series of decisions by this and other courts, if accepted, would excuse from infringement unauthorized uses of the patented invention even if such uses were systematic commercial activities. The CAFC was correct in refusing Bolar's invitation to expand the experimental use exception, or to create a new exception, so as to embrace such systematic commercial activities on the part of Bolar. Moreover, the CAFC reached its conclusion after considering the same cases and arguments relied on in Bolar's petition and discussed *infra.*

Bolar implies that the *only* right of the patent holder is "a right to be free from competition in the practice of the invention" during the term of the patent, (Pet. at 12,14) citing *Mercoid Corp.* v. *Mid-Continent Investment Co.,* 320 U.S. 661, 665 (1944), and that Bolar's use does not interfere with that right (Pet. at 13). These arguments are predicated on a misreading of *Mercoid* and a fundamental misapprehension of the patent law.

First, *Mercoid* does not hold that the *only* right a patentee has is the right to be free from competition in the marketplace. In *Mercoid, supra,* at 665, Justice Douglas actually wrote that "*a right*" conferred by a patent is the right to be free from competition, *i.e.,* the right to exclude others from selling. The opinion nowhere stated or indicated that this was the *only* right. The CAFC also held expressly there need not be sales or competition or profit in order to have infringement (4a).[10]

---

[10] Such has been the law as enunciated in numerous decisions decided before and after *Mercoid. See, e.g., Beedle* v. *Bennett,* 122 U.S. 71 (1887) (competition or profit not required); *Neff Instrument Corp.* v. *Cohu Electronics, Inc.,* 269 F.2d 668, 673 (9th Cir. 1959) (sales not required); *Becton Dickinson & Co.* v. *R.P. Scherer Corp.,* 211 F.2d 835, 842 (6th Cir. 1954) (sales not required); *Del Mar Engineering Laboratories* v. *Physio-Tronics, Inc.,* 202 U.S.P.Q. 242, 260 (C.D. Cal. 1978), *aff'd,* 642 F.2d 1167 (9th Cir.

(footnote continues)

Second, the statute itself establishes that the right to exclude others from selling the patented invention is only one of several rights and not the *only* right granted the patentee. The statute gives the patentee the right to exclude others from making *or* using *or* selling the invention. 35 U.S.C. § 271(a). These rights are property rights, 35 U.S.C. § 261, and are severable. "The right to manufacture, the right to sell, and the right to use are each substantive rights, and may be granted or conferred separately by the patentee." *Adams* v. *Burke*, 84 U.S. 453, 456 (1873).[11]

Furthermore, the existing case law does not support Bolar's claim that it has a right to use a patented product for commercial exploitation. *Kaz Mfg. Co., Inc.* v. *Chesebrough-Pond's, Inc.*, 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd*, 317 F.2d 679 (2d Cir. 1963), cited by Bolar, is inapposite. There the defendant had purchased the product from the patentee and had thereby acquired an implied license to use it. *See Keeler* v. *Standard Folding Bed Co.*, 157 U.S. 659 (1895). Here, Bolar's purchase of flurazepam was from an unauthorized source and Bolar cannot claim any implied license to use. Moreover, the challenged use in *Kaz* consisted of a single isolated use for the purpose of a comparative television advertisement. It was not the systematic exploitation contemplated by Bolar in this case.

(footnote continued)

1981) (sales not required); *Technicon Instruments Corp.* v. *Coleman Instruments, Inc.*, 255 F. Supp. 630, 641-42 (N.D Ill. 1966), *aff'd*, 385 F.2d 391 (7th Cir. 1967) (sales not required); *Carter Crume Co., Ltd.*, v. *American Sales Book Co.*, 124 F. 903, 904 (C.C.W.D.N.Y. 1903) (sales not required); *Flat Slabs Patents Co.* v. *Wright, Barrett & Stilwell Co.*, 283 F. 345, 349 (D. Minn. 1920) (competition or profit not required); *Albright* v. *Celluloid Harness-Trimming Co.*, 1 F. Cas. 320 (C.C.D.N.J. 1887) (No. 147) (damage or profit not required).

[11] Still another valuable right conferred by a patent is the right to grant licenses. Thus, "the patentee may grant a license . . . for any royalty, or upon any condition the performance of which is reasonably within the reward which the patentee by the grant of his patent is entitled to secure." *United States* v. *General Electric Co.*, 272 U.S. 476, 489 (1926).

Akro Agate Co. v. *Master Marble Co.,* 18 F. Supp. 305 (N.D. W. Va. 1937), is also inapplicable. The patent in that case was held invalid and the defendant experimented only briefly with an infringing apparatus, abandoning it in favor of a non-infringing alternative. The case of *Maxon Premix Burner Co.* v. *Eclipse Fuel Engineering Co.,* 471 F.2d 308 (7th Cir. 1972), *cert. denied,* 410 U.S. 929 (1973), similarly does not address the issue of systematic exploitation. It concerned a single isolated sale made nine years earlier—"if there was in fact such a sale." *See also Celotex Corp.* v. *V.E. Power Door Corp.,* 204 U.S.P.Q. 636, 638 (E.D.N.Y. 1979) (a single demonstration or trial conducted years earlier).

Bolar also relies upon *Levin* v. *Ripple Twist Mills, Inc.,* 416 F. Supp. 876 (E.D. Pa. 1976), *appeal dismissed,* 549 F.2d 795 (3d Cir. 1977). In *Levin,* however, the court states, in *dictum,* that an experimental use is not actionable unless and until there is a "commercially valuable use." 416 F. Supp. at 881 n.9. Bolar's use is commercially valuable because the test data generated by the use and the FDA approval based upon such test data are *per se* valuable. Each can be assigned or otherwise transferred for consideration.

The CAFC was correct in refusing to excuse Bolar's unauthorized use because Bolar's use *does* interfere with the patentee's statutory right to exclude others from such use.

IV

THERE IS NO CONFLICT BETWEEN THE CAFC'S DECISION AND DECISIONS OF THIS COURT PROHIBITING THE EXTENSION OF PATENT "MONOPOLIES"

Bolar's claim that the decision below extends patent "monoplies" is unfounded. This case is unlike *Brulotte* v. *Thys Co.,* 379 U.S. 29 (1964), cited by Bolar, which involved *post*-expiration royalty and resale restraints imposed by the patentee which would have extended an expired patent. No such post-expiration restraints are sought by Roche Products or sanctioned by the CAFC here. The decision below merely enforces the patentee's statutory right to exclude others from using the invention *during* the term of the patent. *Scott Paper Co.* v. *Marcalus Mfg. Co.,* 326 U.S. 249 (1945), also relied upon by Bolar, was concerned with an attempt to assert a patent against an allegedly infringing machine that was already in the public domain, because "it . . . [the machine's construction] was precisely that of an *expired* patent." 326 U.S. at 254 (emphasis added). In contrast, Roche Products, in seeking only to enforce its statutory right to exclude infringing use of the patented compound *during* the term of an admittedly valid patent, takes nothing from the public domain.[12]

It has long been held by various courts that a patent holder can exercise its right to seek relief during the patent term even though the sale relating to the infringement occurred after the patent expired or occurred outside the geographic area of patent protection. *See, e.g., Radio Corp. of America* v. *Andrea,* 15 F. Supp. 685 (E.D.N.Y. 1936), *modified on other grounds,* 90 F.2d 612 (2d Cir. 1937) (use of patented invention by testing in preparation for non-infringing extraterritorial sale held infringement); *Fulton Co.* v. *Bishop & Babcock Co.,* 17 F.2d 1006 (6th Cir. 1927) and *Motion Picture Patents Co.* v. *Centaur Film Co.,* 217 F. 247 (D.N.J. 1914) (pre-expiration use of patented invention held infringement and authorizing injunction against non-infringing post-expiration sale); *Underwood Typewriter Co.* v. *Elliott-Fisher Co.,* 156 F. 588 (C.C.S.D.N.Y. 1907) (pre-expiration making of patented invention for non-infringing post-expiration sale held infringement).

There is thus no extension of any patent "monopoly" involved in this case nor is there any conflict between the decision below and decisions of this Court, notwithstanding Bolar's assertions to the contrary.

---

[12] For similar reasons, none of the remaining cases cited by Bolar is applicable. Indeed, none involved questions of patent infringement. *See Singer Mfg. Co.* v. *June Mfg. Co.,* 163 U.S. 169 (1896) (trademark case); *Kellogg Co.* v. *National Biscuit Co.,* 305 U.S. 111 (1938) (trademark case); *Upjohn Mfg. Co.* v. *Schweiker,* 681 F.2d 480 (6th Cir. 1982) (FDA marketing case not involving patents).

CONCLUSION

For the reasons stated above, the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

JOHN C. VASSIL,
(Counsel of Record)
STEPHEN R. SMITH
J. ROBERT DAILEY
JANET DORE
Attorneys for Respondent
Roche Products Inc.

Of Counsel:

JACK LIPSON
MICHAEL T. SHOR
RALPH N. DEL DEO

(2)

No. 84-130

Office - Supreme Court, U.S.
FILED
AUG 31 1984
ALEXANDER L. STEVAS
CLERK

In The

Supreme Court of the United States

◆

October Term, 1984

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

vs.

ROCHE PRODUCTS, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR THE GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION AS AMICUS CURIAE

ALFRED B. ENGELBERG
AMSTER, ROTHSTEIN & ENGELBERG
Attorneys for the Generic
Pharmaceutical Industry
Association as Amicus Curiae
90 Park Avenue
New York, New York 10016
(212) 697-5995

0907
Inta Appellate Printers, Inc. • NJ (201) 257-6850 • NY (212) 840-9494 • PA (215) 563-5587
MA (617) 542-1114 • DC (202) 783-7288 • USA (800) 5 APPEAL

TABLE OF CONTENTS

Page

Preliminary Statement 1

Interest of Amicus Curiae 2

Summary of Argument 4

Argument 6

I. Bolar's acts are not an infringing use of the patented invention 6

II. The lack of economic harm is confirmed by the past inaction of Roche and other drug patent owners. . 11

Conclusion 15

TABLE OF CITATIONS

Cases Cited:

Akro Agate Company v. Master Marble Company, 18 F. Supp. 305 (N.D.W.Va. 1937) 6

Brulotte v. Thys Co., 379 U.S. 29 (1964) 10

Celotex Corporation v. V.E. Power Door Corp., 204 U.S.P.Q. 636 (E.D.N.Y. 1979) 6

Eli Lilly v. Generix Drug Sales Inc., 324 F. Supp. 715 (S.D. Fla. 1971) 12

Page

Finney v. United States, 194 U.S.P.Q. 197 (Ct. Cl. 1976) 10

Hoffmann-LaRoche Inc. v. Zenith Laboratories, Inc., Civil Action No. 75-96 (D.N.J.) 12

Imperial Chemical Industries, PLC v. Henkel Corporation, 545 F. Supp. 635 (D. Del. 1982) 10

Kaz Manufacturing Co., Inc. v. Chesebrough-Ponds, Inc., 211 F. Supp. 815 (S.D.N.Y. 1962), aff'd, 317 F.2d 679 (2d Cir. 1963) 6

Levin v. Ripple Twist Mills, 416 F. Supp. 876 (E.D. Pa. 1976), dismissed without opinion, 549 F.2d 795 (3rd Cir. 1976) 6

Maxon Premix Burner Company, Inc. v. Eclipse Fuel Engineering Co., 471 F.2d 308 (7th Cir. 1972) 6, 10

Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661 (1944) 6

Pfizer v. International Rectifier Co., 217 U.S.P.Q. 157 (C.D. Cal. 1982) 14

Roche Products, Inc. v. Zenith Laboratories, Inc., Civil Action No. 84-2754 (D.N.J.) 13

Scott Paper Co. v. Marcalus Co., 326 U.S. 249 (1964) 10

Contents

Page

Smith, Kline & French Laboratories v. A.H. Robins Co., 61 F.R.D. 24 (E.D. Pa. 1973) 13

Sony Corp. of America v. Universal City Studios, Inc., ___ U.S. ___ (1984) 4, 7, 9

Underwood Typewriter Co. v. Elliott-Fisher Co., 156 F. 588 (C.C. S.D.N.Y. 1907) 9

United States v. Generix Drug Sales Inc., ___ U.S. ___, 75 L. Ed. 2d 198 (1983) 2

Upjohn Mfg. Co. v. Schwerker, 681 F.2d 480 (6th Cir. 1982) 10, 11

Statutes Cited:

21 U.S.C. §321, *et seq.* 2

35 U.S.C. §154 6

35 U.S.C. §271 8

United States Constitution Cited:

Article 1, Section 8 8

Rule Cited:

Supreme Court Rule 36.1 1

Page

Other Authorities Cited:

69 C.J.S. Patents, p. 172 6

3 Robinson, The Law of Patents for Useful Inventions, §898 (1890) 7

Warner, Consumer Protection and Prescription Drugs: The Generic Substitution Laws, 67 Kentucky Law Journal 389 (1979) 4

Staff Report to the Federal Trade Commission, Drug Product Selection (1979) 4

APPENDIX

Appendix A 1a

Appendix B 4a

No. 84-130

In The

Supreme Court of the United States

◆

October Term, 1984

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

vs.

ROCHE PRODUCTS, INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR THE GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION AS AMICUS CURIAE

PRELIMINARY STATEMENT

This amicus brief is presented by the Generic Pharmaceutical Industry Association pursuant to Rule 36.1 of the Supreme Court Rules with the written consent of both parties on file with the Clerk of this Court. This brief supports the petition of Bolar

Pharmaceutical Co., Inc. that a writ of certiorari issue to review the decision of the Court of Appeals for the Federal Circuit which was entered on April 23, 1984.

INTEREST OF AMICUS CURIAE

The Generic Pharmaceutical Industry Association (GPIA) was formed in 1980 by a group of independent generic drug manufacturers, distributors and retailers. It now includes about 85% of the independent generic drug industry, and represents the interests of that industry in legislative, judicial and administrative forums.

The prescription drug products marketed by GPIA members must be approved by the Food and Drug Administration (FDA) with respect to safety and effectiveness before those products may be manufactured and sold.[1] This pre-marketing approval requirement applies to essentially all prescription drug products, including generic drugs, *i.e.,* drugs which are the chemical and therapeutic equivalent of an existing and previously approved brand name drug product. Under FDA regulations, a GPIA member company seeking approval to sell a generic version of a previously marketed brand name drug product must develop and submit data to the FDA sufficient to establish that the generic drug product can be commercially produced in a chemically stable form and that the active drug ingredient gets into the body in the same amount and at the same speed as the existing brand name product. It is generally recognized that at least about two (2) years will elapse between the date when a company first decides to market a new generic drug and the date of actual FDA approval.

---

[1] Federal Food Drug and Cosmetic Act, 21 U.S.C. §321, *et seq.*

The sale of a drug product without such approval is a crime, and the products are subject to seizure.[2]

The decision below holds Bolar liable for patent infringement based solely on the pre-patent expiration testing activities which were undertaken to obtain FDA approval to market a generic version of flurazepam hydrochloride. It is beyond dispute that none of Bolar's testing activities prior to the patent expiration date reduced Roche's market by a single tablet during the life of the Roche patent. Indeed, none of those activities resulted in the production of a single tablet which was used or sold for therapeutic purposes either before or after the patent expiration date. In short, Bolar sought only to place itself in a position to engage in legitimate competition with Roche at the earliest possible date after the Roche patent expired without depriving Roche of any of the economic benefits of its patent rights prior to that expiration date.

The decision of the Federal Circuit has a substantial adverse impact which extends well beyond the specific parties and drug product involved in this litigation. It upsets the common and long-standing testing practices of generic drug manufacturers and promises to spawn a significant amount of unwarranted litigation with respect to past testing activities which everyone believed to be permissible. Until this case, no drug patent owner ever sought to prevent FDA testing prior to patent expiration even though it was well known that such testing was common and drug patent infringement claims were otherwise being vigorously pursued. This new wave of litigation (which has already begun) is designed and intended to wrongfully extend the effective life of a patent monopoly beyond its expiration date, thereby frustrating the "limited" monopoly provisions of the Constitution, this Court's rigorous adherence to the constitutional concept of a time limited monopoly, and the public policy favoring the availability of lower costing generic drugs.[3]

---

[2] *United States v. Generix Drug Sales Inc.*, ____ U.S. ____, 75 L. Ed. 2d 198 (1983).

SUMMARY OF ARGUMENT

The purpose of the patent law is to provide incentives for creative effort, but a use of a patented invention that has no demonstrable effect on the potential market for, or value of, the patented invention need not be prohibited to protect that incentive. This principle was recently reaffirmed by this Court in a copyright case[4] and applies with equal force to patents, since both forms of intellectual property have a common constitutional origin and purpose. Indeed, the judicially developed doctrine of *de minimis* or experimental use in patent cases is completely analogous to the "fair use" doctrine of copyright law and both doctrines should logically be governed by a common set of principles. Those principles establish that testing activities which in no way diminish the patent owner's ability to profit from the demand for the patented invention during the life of a patent are not actionable even though they may, in a purely technical sense, infringe on the statutory rights granted to the patent owner.

The Federal Circuit failed to reach the right conclusion in this case only because it literally construed the word "use" in the patent law and placed unwarranted emphasis on the ultimate post-patent expiration commercial purpose of Bolar's experiments. In so doing, it disregarded the fact that Bolar's testing activity did not in any way diminish the market for the patented Roche drug during the life of the Roche patent and that Roche lost no profits and suffered no other injury whatsoever during the life of its patent. The Constitution commands that the patent monopoly last for only a limited time and that the public may then enjoy full access to the patented invention. By relying on Bolar's commercial intentions after the Roche patent expired rather than focusing on Bolar's activities during the life of the patent, the Federal Circuit improperly extended the effective life of the Roche patent.

---

[3] Staff Report to the Federal Trade Commission, Drug Product Selection (1979); Warner, *Consumer Protection and Prescription Drugs: The Generic Substitution Laws,* 67 Kentucky Law Journal 389 (1979).

[4] *Sony Corp. of America v. Universal City Studios, Inc.,* ____ U.S. ____ (1984).

In reaching its erroneous decision, the Federal Circuit ignored the best evidence that FDA testing causes no injury and should not be actionable. That evidence consists of the failure of Roche and other drug patent owners to ever before assert a patent infringement claim based on FDA testing activities or to even seek damages or other relief for such testing activities in proven cases of commercial patent infringement. Despite the zealous enforcement of patent rights by drug patent owners, no reported case involving the enforcement of a drug patent grants any relief with respect to any acts undertaken by an infringing generic company to obtain FDA approval to market a drug covered by an unexpired patent. That such approvals have been routinely sought and granted for many years is common knowledge in the pharmaceutical industry. Indeed, prior to the present case, even Roche publicly took the position that seeking FDA approval to market a patented drug product was a legitimate activity and not an act of patent infringement. It took that position in a case involving Valium, the most financially important drug in the recent history of Roche.

ARGUMENT

I.

Bolar's acts are not an infringing use of the patented invention.

The grant of a patent conveys the right "to exclude others from making, using or selling the invention. . . " 35 U.S.C. §154. This Court has characterized that right as the "right to be free from competition in the practice of the invention." *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944); *see also, Kaz Manufacturing Co., Inc v. Chesebrough-Ponds, Inc.*, 317 F.2d 679 (2d Cir. 1963). Put another way, a patent "insures against another doing substantially the same thing in substantially the same way as the patentee." 69 C.J.S. *Patents,* p. 172, quoted in *Kaz Manufacturing Co., Inc. v. Chesebrough-Ponds, Inc.*, 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd,* 317 F.2d 679 (2d Cir. 1963).

The crucial factor historically relied on by courts in determining whether a charged activity constitutes "use" within the meaning and intent of the patent laws, is the purpose and effect of the use. The courts have consistently upheld the public's right to use a patented article for purposes which do not disturb the patentee's enjoyment of the exclusive privileges secured by a patent while variously characterizing such accused, but non-infringing uses, as *de minimis,* experimental, outside the scope of the patent or in the public interest. *Kaz Manufacturing Co., Inc. v. Chesebrough-Ponds, Inc., supra; Celotex Corporation v. V.E. Power Door Corp,* 204 U.S.P.Q. 636 (E.D.N.Y. 1979); *Levin v. Ripple Twist Mills,* 416 F. Supp. 876 (E.D. Pa. 1976), *dismissed without opinion,* 549 F.2d 795 (3rd Cir. 1976); *Akro Agate Company v. Master Marble Company,* 18 F. Supp. 305 (N.D.W.Va. 1937); *Maxon Premix Burner Company, Inc. v. Eclipse Fuel Engineering Co.,* 471 F.2d 308 (7th Cir. 1972).

The foregoing principles, which collectively establish that not every literal "use" of a patented invention amounts to patent infringement, were succinctly summarized almost 100 years ago in 3 Robinson, *The Law of Patents for Useful Inventions*, §898 (1890) as follows:

> "The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of pecuniary character. . . . Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one."

Recently, this Court had the opportunity to evaluate the question of whether every literal "use" of a copyrighted work constitutes infringement or whether there are certain "fair uses" which carry no such liability. *Sony Corp. of America v. Universal City Studios, Inc.*, ____ U.S .____(1984). In language strongly supportive of the Robinson patent textbook, this Court held:

> "The purpose of copyright is to create incentives for creative effort. Even copying for noncommercial purposes may impair the copyright holder's ability to obtain the rewards that Congress intended him to have. But a use that has no demonstrable effect upon the potential market for, or the value of, the copyrighted work need not be prohibited in order to protect the author's incentive to create. The prohibition of such noncommercial uses wouuld merely inhibit access to ideas without any countervailing benefit."

The striking similarity between the "fair use" doctrine in copyright law and the experimental or *de minimis* use doctine in patent law is no accident. Rather it is the natural outgrowth of the fact that both forms of intellectual property are derived from the same constitutional provision (Article 1, Section 8) and the consistent recognition by this Court of the special and limited nature of these intellectual property monopolies. As this Court stated in *Sony* with respect to both patents and copyrights:

> "The monoply privileges that Congress may authorize are neither unlimited nor primarily designed to provide a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved. It is intended to motivate the creative activity of authors and inventors by the provision of a special reward, and to allow the public access to the products of their genius after the limited period of exclusive control has expired."

Clearly, both the "fair use" and "experimental use" doctrines are merely a prudent judicial attempt to augment the efforts of Congress in striking the appropriate balance between the competing interests of authors or inventors on the one hand and the public on the other.

The Federal Circuit, while giving lip service to all of the foregoing principles, nevertheless gave a literal construction to the word "use" in Section 271 of the Patent Law. It permitted itself to be unduly influenced by the fact that Bolar's purpose in doing FDA testing was to ultimately engage in a commercial enterprise while totally failing to consider the fact that this commerce would not begin until long after the Roche patent expired. The Circuit Court failed to recognize that the FDA testing activities of Bolar and Bolar's eventual manufacture and sale of the drug after receiving FDA approval are distinct events which are separated by an even more important event — the expiration of the Roche patent.

The pre-expiration testing activities do not injure Roche because, as in *Sony*, they have no demonstrable effect on the market for, or value of the patented invention during the life of the Roche patent. The eventual competitive commercial activities of Bolar in making, using and selling the drug product after receiving FDA approval are not wrongful and cannot be the cause of any legally cognizable injury to Roche because those activities do not occur until after the Roche patent has expired! The Federal Circuit simply failed to draw the necessary and proper distinction between Bolar's non-infringing acts prior to patent expiration, which are themselves non-injurious, but are designed to hasten legitimate competition after the Roche patent expires, and the commercial acts of Bolar subsequent to patent expiration, which are not acts of infringement because the Roche patent has expired. There is no proper analogy to the so-called "stockpiling" cases[5] because those cases involve an actual act of infringement during the life of a patent, namely, the commercial manufacture of the patented invention. Here, not a single tablet made by Bolar prior to patent expiration will be sold or used for therapeutic purposes either before patent expiration or afterward.

The Federal Circuit also failed to recognize that FDA approval does not require Bolar to engage in commercial manufacture, use or sale of the approved drug product. It merely provides Bolar with the privilege of doing so. If Bolar obtained FDA approval during the first year of the Roche patent and thereafter engaged in no other activity for sixteen (16) years until the patent expired,

---

5. *See, e.g., Underwood Typewriter Co. v. Elliott-Fisher Co.*, 156 F. 588 (C.C. S.D.N.Y. 1907).

its actions would clearly be characterized as *de minimis* on the ground that they amounted to nothing more than an activity which was terminated before it had advanced to a stage where it invaded the patentee's exclusive rights. *Cf.*, *Imperial Chemical Industries, PLC v. Henkel Corporation,* 545 F. Supp. 635 (D. Del. 1982); *Maxon Premix Burner Company, Inc. v. Eclipse Engineering Co., supra; Finney v. United States,* 194 U.S.P.Q. 197 (Ct. Cl. 1976). The acts involved in obtaining FDA approval and commercialization will follow each other without interruption in this case solely because the Roche patent will expire by the time FDA approval is obtained. Surely, the fact that Roche's patent was about to expire did not give Roche greater rights or change the *de minimis* character of Bolar's pre-expiration acts. Preparation for legitimate competition is not infringement and cannot properly be combined with activities following patent expiration so as to reach a contrary conclusion. Indeed, any protection against post-expiration competition is contrary to established federal policy. As this Court stated in *Scott Paper Co. v. Marcalus Co.,* 326 U.S. 249, 256 (1964):

> ". . . any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws."

See also, Brulotte v. Thys Co., 379 U.S. 29 (1964).

In the final analysis, the Federal Circuit placed unwarranted emphasis on the fact that Bolar will benefit from its FDA testing activities because it will be able to compete with Roche at an earlier date after the patent expires. But, FDA pre-marketing approval regulations were enacted to protect the health and safety of the public and not for the purpose of extending the life of patent monopolies. *Upjohn Mfg. Co. v. Schwerker,* 681 F. 2d 480 (6th

Cir. 1982). Roche has no standing to complain about when, where or how Bolar satisfies FDA requirements or commences competition, provided that Roche is free of competition during the life of the Roche patent.

The District Court below correctly perceived the significance of all of the foregoing facts and made the following holding:

> "More importantly, the court cannot find a basis for holding that Bolar's limited experimental use of flurazepam hcl would constitute infringement. First, Bolar realizes no benefit during the term of the patent; its activities are in no way connected with current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the patent law. This court will not act to protect a right or benefit that is without legal basis. Third, Roche can point to no substantial harm it will suffer from Bolar's FDA studies before the patent expires. Bolar's threatened activity is at best *de minimis* and will not support an action for infringement."

The District Court should have been affirmed.

II.

The lack of economic harm is confirmed by the past inaction of Roche and other drug patent owners.

The Federal Circuit decision below upsets the long prevailing pharmaceutical industry practice of conducting required FDA testing prior to patent expiration. Appendix A hereto is a small sample of publicly available information which establishes (based on FDA filing and approval dates and patent expiration dates) that such testing has been common. In reviewing this exemplary but non-exhaustive list, it is of more than passing interest that it includes Librium (a Roche product) and other products which have been involved in patent infringement litigation. Yet, none of those cases[6] involved any request for (or grant of) relief aimed at the FDA testing activities of the infringer. Certainly, there was no effort by Roche, as there is here, to seek an order destroying FDA test data or otherwise prohibiting its use.

Any doubt about the unprecedented nature of the Federal Circuit's decision in this case will be quickly put to rest by considering the statements and actions of Roche with respect to the FDA testing activities in a case which involved the alleged infringement of the patent covering Roche's most financially important product — Valium. In *Hoffman-LaRoche, Inc. v. Zenith Laboratories, Inc.*, Civil Action No. 75-2221 (D.N.J.), Zenith sought a declaratory judgment dismissing Roche's claim that its patent covering Valium was infringed on the ground that it had only engaged in FDA testing activities and that such activities did not constitute infringement. In a memorandum in support of a Rule 12 motion seeking to dismiss Zenith's counterclaim, Roche stated:

> "It has been clear from the outset of this case that *Roche does not seek to interfere with Zenith's legitimate activities in seeking F.D.A. approval of a New Drug Application (NDA) for diazepam.* Nor has Roche done anything to interfere with Zenith's bidding for U.S. government contracts. Roche's

---

[6] *Hoffmann-LaRoche Inc. v. Zenith Laboratories, Inc.*, Civil Action No. 75-96 (D.N.J.) (Librium); *Eli Lilly v. Generix Drug Sales Inc.*, 324 F. Supp. 715 (S.D. Fla. 1971) (Darvon).

> brief in opposition to Zenith's Rule 12 motion expressly states:
>
> 'Roche does not seek to enjoin Zenith from doing the experimental work necessary for it to secure F.D.A. approval or from bidding for U.S. government contracts.' (p. 5)." (Emphasis added.)

A consent judgment which was subsequently entered in the foregoing Valium case (Appendix B) contains an express acknowledgment of Zenith's prior FDA testing activity as well as Zenith's intention to continue with such testing. It also includes a provision (paragraph 9) permitting Zenith to retain 5 kilograms of raw material for permissible experimentation under the patent laws. Although litigation is now pending to construe the meaning of that consent judgment,[7] the inconsistency between Roche's position in the Valium case and the present case is apparent on its face.

Apart from the foregoing, a search for prior decisions specifically involving the question of whether FDA testing constitutes infringement reveals the existence of only two decisions. In the first case, *Smith, Kline & French Laboratories v. A.H. Robins Co.*, 61 F.R.D. 24 (E.D. Pa. 1973), SK&F, a large research-oriented pharmaceutical company which owns many patents, moved to strike a claim of patent infringement, as a matter of law, on the ground that the manufacture or use of a patented drug product for the purpose of conducting tests to obtain FDA approval is an experimental use and not an infringement. The SK&F motion was denied only because the court lacked evidence as to whether the FDA approval process involved any distribution of the patented drug which was arguably commercial. Here, it is stipulated that no such distribution occurred.

---

[7] *Roche Products, Inc. v. Zenith Laboratories, Inc.*, Civil Action No. 84-2754 (D.N.J.).

In the second case, *Pfizer v. International Rectifier Co.*, 217 U.S.P.Q. 157 (C.D. Cal. 1982), experimental use was asserted as a defense to a contempt proceeding involving alleged violations of an injunction against patent infringement. The defendant in *Pfizer* had engaged in a variety of clearly commercial activities in addition to alleged FDA experimentation, and the District Court's discussion of the experimental use issue was dicta. For that reason, the *Pfizer* decision was ignored by both the District Court and the Federal Circuit in reaching their respective and differing decisions in this case.

In summary, every available objective fact establishes that generic drug manufacturers have openly and publicly engaged in pre-patent expiration FDA testing activities, and that drug patent owners have long acquiesced in such testing. The obvious reason for that circumstance is that no one believed that such testing harmed any legitimate or protectable interest of a patent owner. The Federal Circuit should have been guided by this rather clear indication of the *de minimis* nature of the alleged offense. Instead, it chose to treat a patent as an inviolable property right which is entitled to enforcement without regard to economic harm. The court's narrow viewpoint is highlighted by its refusal to credit the candid admission by Roche's counsel that the monetary harm suffered by Roche as a result of Bolar's testing was nominal.

CONCLUSION

This case involves an important question as to the proper balance between the rights of patent owners and the rights of the public. It was decided below in a manner which upsets both the settled expectations of the affected industry and the consistent policy of this Court in preventing attempts to extend the life of a patent. Accordingly, the requested writ of certiorari should be granted.

Respectfully submitted,

s/ Alfred B. Engelberg
AMSTER, ROTHSTEIN &
ENGELBERG
Attorneys for the Generic
Pharmaceutical Industry
Association as Amicus Curiae

APPENDIX A

GENERIC DRUG TESTING AND APPROVAL PRIOR TO EXPIRATION OF PATENT ON BRAND NAME DRUG

BRAND NAME DRUG (Generic Drug)	PATENT OWNER FIRM Generic Firm	DOSE	FDA Application Submission with test data	Date Of FDA Aplication Approval	Patent Expiraation
LIBRIUM (Chlordiazepoxide HCL)	ROCHE	5 mg	12/59	4/60	7/76
		10 mg	12/59	2/60	
		25 mg	12/59	5/60	
	Barr	10 mg	7/72	6/76	
	Zenith	5-10 mg	5/73	3/75	
	Parke Davis	5-10 mg	12/74	8/76	
	Mylan	10 mg	12/74	3/76	
DARVON (Propoxyphene HCL)	LILLY	32-65 mg	3/57	8/57	12/72
	Zenith		1/71	11/71	
	Lederle		7/71	9/72	
	Danbury		2/72	8/72	
	Roxane		6/72	8/73	
	Cord		7/72	10/72	
	Bolar		7/72	12/72	
ORANASE (Tolbutamide)	UPJOHN		8/56	5/57	1/78
	Warner Lambert		9/77	11/79	
	Mylan		6/78	4/79	
	Chelsea		10/77	1/79	
	SKF		11/77	8/79	
	Cord		4/78	6/80	
	Zenith		7/79	3/80	

Appendix A

ALDACTAZIDE (Hydrocholorothazide)	SEARLE		9/60	9/62	12/78
	Bolar		7/77	2/79	
	Chelsea		8/77	4/81	
	Mylan		7/78	8/79	
	Cord		1/79	7/80	
	Zenith		4/79	5/80	
	Barr		2/80	4/81	
HYGROTON (Clorthalidone)	USV	100 mg	1/60	4/60	9/79
		50 mg	1/60	7/67	
		25 mg	12/77	9/79	
	Mylan	50 mg	1/79	2/81	
		25 mg	11/79	2/81	
	Bolar	25 mg	6/79	3/81	
		50 mg	5/79	3/81	
	Zenith	50 mg	10/79	4/81	
	Barr	25-50 mg	3/80	3/81	
PERSANTINE (Dipyridamole)	BOEHRINGER-INGELHEIM	25 mg	4/61	12/61	4/79
	Pharmadine		1/79	9/79	
	Premo		2/79	10/79	
	Cord		3/79	8/80	
	Bolar		4/79	9/79	
	Zenith		4/79	9/79	
	Chelsea		6/79	9/79	
	Par		7/79	9/79	
MELLARILL (Thioridazine)	SANDOZ	10-25 mg	12/58	5/59	3/83
		100-150 mg			
		50 mg	12/58	6/70	

		200 mg	12/58	5/61	
	Mylan	10-25-50 mg	6/82	3/83	
	Cord	10-25-50 mg	9/82	8/83	
	Zenith	50 mg	11/82	4/83	
DIABINASE (Chlorpropamide)	PFIZER		8/58	10/58	10/84
	Premo		3/75	7/80	
	Chelsea		11/79	10/80	
	Pharmadine		2/80	11/80	
	Zenith		6/80	6/81	
	Par		10/82	2/84	
VIBRAMYCIN (Doxycyline)	PFIZER	50 mg	6/66	12/67	8/82
		100 mg	6/66	8/68	
	Rachelle		2/73	7/73	
	Chelsea		8/78	8/81	
	Danbury		12/76	2/77	
	Lemmon		6/79	12/79	
	Barr		9/82	1/83	
	Mylan		10/81	3/82	
ALDOMET (Methyldopa)	MERCK	125 mg	12/73	1/75	9/84
		250 mg	2/62	12/62	
	Cord	250 mg	1/83	6/84	
		500 mg	1/83	6/84	

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

(Hon. Frederick B. Lacey)

Civil Action
No. 75-2221

HOFFMAN-LA ROCHE INC., a corporation,

Plaintiff,

-vs-

ZENITH LABORATORIES, INC., a corporation,

Defendant.

CONSENT JUDGMENT

WHEREAS, the above entitled action was brought by Hoffman-La Roche Inc. (hereinafter "Roche"), as plaintiff, against Zenith Laboratories, Inc. (hereinafter "Zenith"), as defendant, charging Zenith with having taken steps and made arrangements and preparations to infringe United States Letters Patent No. 3,371,085, owned by Roche, and with infringement thereof; and

WHEREAS, Zenith has answered the complaint, denying the aforesaid allegations, and has asserted affirmative defenses including absence of a case or controversy, that the Court ought not to exercise its discretionary jurisdiction because the threat of infringement by Zenith is too speculative and abstract, that Zenith's application to the United States Food and Drug Administration for approval to market and distribute diazepam is privileged, that Roche is barred from obtaining any remedy in this Court for Zenith's actions by reason of 28 U.S.C. §1498(a), and that Roche is precluded from enforcing said patent because the same is invalid and void for failure to meet the statutory requirements for issuance thereof, for misuse of the patent and for violation of the antitrust laws of the United States; and

WHEREAS, Zenith has asserted counterclaims against Roche alleging a malicious course of conduct to harass Zenith, unfair competition and restraint of trade in violation of the antitrust laws of the United States and of the common law of the State of New Jersey, and has sought relief including treble damages and judgment that Zenith's activities in connection with its importation of diazepam, its FDA application and sale to the United States Government do not constitute patent infringement; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that upon entry of this Judgment, it will deliver up to Roche from the United States, its territories and possessions, all diazepam in its possession, custody or control, in bulk form for which it shall be reimbursed by Roche in the amount of twenty-five thousand dollars ($25,000); F.O.B. our plant in the Virgin Islands and

WHEREAS, Roche has replied to Zenith's counterclaims, denying all allegations of illegality, impropriety, inequitable conduct and liability contained therein, and has asserted affirmative defenses including that the Court lacks jurisdiction over the second counterclaim; and

Appendix B

WHEREAS, discovery has been conducted on the issues framed by the complaint, answer, affirmative defenses, counterclaims and replies thereto, and the parties have additionally had the benefit of prior discovery of each other in Civil Action No. 75-96 in this Court; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that said United States Letters Patent No. 3,371,085 are good, valid and enforceable; that diazepam is disclosed and claimed in said Letters patent; and that Roche is the owner of said Letters Patent and is solely entitled to recover for infringement of said Letters Patent; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that Zenith has imported into the United States, its territories or possessions, a quantity of diazepam is excess of 500 kilograms (more than half a ton); that Zenith has manufactured, from a part thereof, pharmaceutical dosage form units suitable for administration to humans, including some 100,000 tablets each containing two milligrams of diazepam as the active ingredient, some 100,000 tablets each containing five milligrams of diazepam as the active ingedient, and some 100,000 tablets each containing ten milligrams of diazepam as the active ingredient; that Zenith has used several thousand of said tablets for the purpose of obtaining data and information demonstrating the pharmacological efficacy and suitability for administration of such tablets to humans, the portion so used amounting to approximately 0.19 kilogram of diazepam (less than 0.04% of the amount imported); that Zenith's remaining stock of diazepam is sufficient for it to manufacture more than 250,000,000 tablets each containing two milligrams of diazepam as the active ingredient; that Zenith has made application to the United States Food and Drug Administration for approval to market and distribute diazepam in dosage unit form of tablets containing two milligrams, five milligrams, or ten milligrams of diazepam as the active ingredient, and has pursued said application by, *inter alia,* submitted data and information, including that described above, in support thereof; that Zenith's aforesaid acts have all been without leave or license of Roche; and that Zenith has never received the authorization or consent of the United States Government to use or manufacture diazepam in dosage unit form or otherwise; and

WHEREAS, new management has assumed responsibility for the decision making process in Zenith and that management has chosen not to continue with the litigation or contest the validity of Roche patents, the subject of this litigation and desires to settle this litigation; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that the invention disclosed and claimed in said Letters Patent No. 3,371,085 is the invention of Earl Reeder and Dr. Leo Henryk Sternbach, that it was made by them in this country and that said invention is a pioneer invention; and

WHEREAS, Zenith desires to continue in its experimentation with diazepam as hereinafter provided, and will retain in its possession for such use only five (5) kilograms of diazepam; and

WHEREAS, Zenith has represented, and by its consent hereto does hereby represent, that it will not make, use or sell diazepam, either alone or in conjunction with others, and will not assist, aid or abet others to make, use or sell diazepam, in bulk or dosage unit form, either pure or in admixture with other compounds, including excipients, without leave and license of Roche, on or after the date of this Judgment and until expiration of said Letters patent on February 27, 1985; and

WHEREAS, Zenith has acknowledged, and by its consent hereto does hereby acknowledge, that it consents to entry of this Judgment as its free act and deed, without coercion or duress, and that there are no agreements or understandings between the parties, except as part of this Judgment;

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. That this Court has jurisdiction over the parties and the subject matter of this action.

2. That United States Letters Patent No. 3,371,085, issued to Roche on February 27, 1968, are good, valid and enforceable, and that Roche is the owner of said Letters Patent and solely entitled to recover for any infringement thereof.

3. That Zenith, each and every subsidiary thereof and each and every company under its direct or indirect control, their officers, agents, servants, employees, successors and assigns, be, and each of them hereby is, enjoined and restrained, for the duration of said Letters Patent No. 3,371,085 through and including February 27, 1985, from

(a) infringing United States Letters Patent No. 3,371,085 or aiding, assisting or abetting others to infringe said Letters Patent;

(b) inducing or contributing to the infringement by others of United States Letters Patent No. 3,371,085;

(c) making, using, selling, offering for sale, delivering, formulating, encapsulating, tableting, advertising, importing or otherwise obtaining diazepam, or any other substance covered by any claim or claims of United States Letters Patent No. 3,371,085, without leave and license of Roche;

(d) making, using, selling, offering for sale, delivering, formulating, encapsulating, tableting, advertising, importing or otherwise obtaining any product containing diazepam or any other substance covered by any claim or claims of United States Letters Patent No. 3,371,085 as an active ingredient, without leave and license of Roche; and

(e) making, using or selling diazepam, or any other substance covered by any claim or claims of said Letters Patent No. 3,371,085, either alone or in conjunction with others, and will not assist, aid or abet others to make arrangements or preparations for, or take steps, to make, use or sell diazepam, or any other substance covered by any claim or claims of said Letters Patent No. 3,371,085, without leave and license of Roche.

4. That nothing herein shall be construed as limiting, expanding or otherwise affecting any applicability of Title 28, United States Code, Section 1498(a), to Zenith's past or future activities.

5. That nothing herein shall be taken as a waiver or limitation of Roche's right to seek remedy for any sales by Zenith to the

United States Government, or others; and nothing herein shall be taken as the grant of a license, or as the grant or waiver of any rights by Roche.

6. That the answer, affirmative defenses and counterclaims filed by Zenith be dismissed with prejudice in all respects.

7. That no cost, disbursements, attorneys' fees or damages be awarded.

8. That all terms and conditions of this Judgment shall apply to Zenith and each and every subsidiary thereof and each and every company under its direct or indirect control.

9. Zenith may retain in its possession five (5) kilograms of diazepam for the limited purpose of such experimentation as fairly falls within permissible experimentation under the patent laws of the United States. Nothing herein shall prejudice Zenith from taking advantage of its rights, if any, under Title 28 U.S.C. §1498(a). Nothing contained herein [and in particular by way of illustration and not limitation, Paragraphs 3(c), 3(d) and 3(e)] shall be construed as limiting, expanding or otherwise affecting the provisions of this Paragraph 9.

ENTERED as of this 2nd day of August, 1979,

s/ Frederick B. Lacey
United States District Judge

Form, Entry and Substance of the foregoing
Judgment are hereby consented to:

ZENITH LABORATORIES, INC.

By: (illegible)
President

[CORPORATE SEAL]
Attest:

By: (illegible)
Secretary

SILLS, BECK, CUMMIS,
RADIN & TISCHMAN, P.A.

By: (illegible)
A Member of the Firm
Attorneys for Zenith
Laboratories, Inc.

HOFFMAN-LA ROCHE INC.

By: Ellis B. Anderson
Vice-President

[CORPORATE SEAL]
Attest:

By: (illegible)
Assistant Secretary

CRUMMY, DEL DEO,
DOLAN & PURCELL

By: (illegible)
A Member of the Firm
Attorneys for Hoffman-
La Roche Inc.